Clinical Application of Urologic Catheters, Devices and Products

Diane K. Newman
Eric S. Rovner
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Springer

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Preface

There are many "tools" essential to the practice of urology, a surgical specialty that manages patients with acute and chronic genitourinary conditions. Urology providers encounter patients who need to drain a kidney(s), ureter(s), or bladder, or who are managing or preventing urine leakage, or are supporting a vaginal prolapse. But the dilemma for most clinicians is not being aware of available urology tools, such as catheters and other devices and products, and not keeping current with new technological changes to these essential urologic tools.

As a multidisciplinary team with expertise in this area, we felt that a textbook would fill this crucial gap in knowledge by providing extensive information on these tools. This textbook is our collaboration on the "nuts and bolts" of using catheters, devices, and products in men and women with emphasis on urologic use. You will find a comprehensive overview of urologic tools with practical information on the indications, types, sizes, and materials, adverse events and complications, patient education, best practices and evidence-based research, and regulations for use.

This book is unique from other urologic textbooks—which, in most cases, only mention these tools within a chapter on a specific urologic condition (e.g., obstructive uropathy, nephrolithiasis, incontinence)—because it devotes entire chapters to indwelling, intermittent, and external catheters, stents, and tubes, drainage bags, external barrier and internal occlusive urethral devices, intravaginal devices and products, penile compression devices, perineal skin care, and incontinence absorbent products. The book's uniqueness extends to its design as a "picture book," including numerous pictures and illustrations of all aforementioned tools. Additionally, the book includes patient instructions for the application and care of a specific catheter, device, or product, as well as best practices for clinical care.

The book contains eight chapters authored by multidisciplinary professionals with expertise in urologic catheters, devices, and products, including urologists, physiatrists, registered nurses, nurse practitioners, physician assistants, and an individual with expertise in marketing incontinence products. Chapter One describes the use of indwelling urinary catheters (IUCs), transurethral and suprapubic, and details the current evidence-based and regulatory guidelines on the use of IUCs, with specifics on complications such as catheter-associated UTIs. Chapter Two reviews intermittent use of urinary catheters (referred to as intermittent catheterization or IC) by patients performing catheterization during their daily lives. With approximately 12,000 new cases of spinal cord injuries per year, and many more with neurogenic lower urinary tract dysfunction, the first-line bladder management in these patients is intermittent catheterization. The technological advances in catheters used for IC are rapid and evolving. Chapter Three reviews external catheters and pouches, primarily used in men with urinary incontinence. Chapter Four discusses specific catheters and devices, such as dilators, filiforms, stents, and nephrostomy tubes, used to relieve obstruction in the urinary tract. Many of the catheters and devices discussed in Chapters One through Four use some type of urinary drainage bag, which is the topic of Chapter Five. The final three chapters provide further information on devices and products: Chapter Six describes absorbent products used by patients with urinary incontinence before and after treatments; Chapter Seven provides a comprehensive review of many urologic and pelvic devices, including urostomy appliances, penile compression devices,

internal and external inserts and urethral meatus barriers, toileting assistive devices, and intravaginal support devices; and Chapter Eight entails a short review of perineal skin care as it relates to the urologic patient.

The name of manufacturers and/or suppliers of specific catheters, devices or products shown in this book are noted in the Figure legend. Additional information and access to most, if not all of them, is available on the internet. The Continence Product Advisor website (http://www. continenceproductadvisor.org/), a collaboration between the International Continence Society and other organizations, is also a resource educating patients on certain urologic catheters, devices and products.

In sum, this book is a one-of-a-kind, clinically based textbook detailing the latest technology and knowledge on urologic catheters, devices, and products. The book is accessible and easy to understand, with many photos and illustrations to assist in relaying the information. And, most importantly, the book fills a critical void in urology professional education for all urology and other health care providers and their support personnel.

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Indwelling (Transurethral and Suprapubic) Catheters

1

Diane K. Newman, Rebecca Patton Cumbee, and Eric S. Rovner

Description

Indwelling urinary catheters (IUC) are used in selected patients for urinary retention, prevention of upper urinary tract deterioration, comfort in terminally ill patients, and many other indications. IUCs can be made from various materials and come in an array of sizes, shapes and designs allowing for easier insertion, improved patient comfort, and a potential reduction in associated complications. However, despite their widespread use, very little research has been conducted on these commonly used catheters. With recent regulatory and financial pressures directed toward reducing catheter-associated urinary tract infections (CAUTIs) in hospitals, attention has been refocused toward the use of an IUC in this setting. Now, more than ever, research is being conducted to see what measures can be initiated to reduce hospital acquired CAUTIs. Such measures include catheter checklists with algorithms to decrease unindicated catheter use and enhance appropriate and timely removal of catheters when no longer required.

History

Urological problems are protean and have been documented in written human history predating ancient Egypt. In fact, the Hippocratic Oath, recited by the majority of medical school graduates in the United States (US), refers specifically to only two types of clinicians, one of which are "practitioners" of "stone" known in ancient Greece as "lithotomists," but today are known as urologists.

Urinary catheters have been utilized as early as 3000 B.C. The ancient catheters were made out of simple materials such as gold, copper, tin, papyrus, oiled onion stems, and dried reeds, depending upon the natural resources available [1]. Malleable urinary catheters were available by the eleventh century. Benjamin Franklin, the inventor that he was, worked with a silversmith to design a flexible silver catheter for his brother who suffered from kidney stones [2]. It was not until the eighteenth century that urinary catheters were first fashioned from rudimentary rubber materials. Such catheters were not optimal because they became friable and fractured once inside the bladder due to the higher body temperature [3, 4].

Urinary catheters were modernized with the process of vulcanization of rubber, thus stabilizing them at higher temperatures. In the 1930s, Dr. Frederick B. Foley introduced the current iteration of the modern day IUC which was made from latex rubber with a non-disintegrable inflatable balloon at one end. This has been commonly referred to as a Foley or Foley catheter. The design of the balloon (called a retention catheter) allowed for the catheter to remain in place (indwelling in the bladder) with a reasonable degree of patient comfort. Furthermore, such a fixed position permitted external collecting devices (e.g., drainage tubing and bag) to be connected to the catheter. Eventually, the concept of a closed sterile drainage system was introduced which reduced the risk of urinary tract infection (UTI) associated with IUCs.

Catheterization Descriptions

Indwelling catheters are either inserted urethrally (transurethral) or suprapubically (through the abdominal wall). Suprapubic catheterization usually is indicated after bladder, urethral or pelvic surgery, or following genitourinary trauma. In practice, urethral catheterization is the typical approach because the procedure can be organized and managed by

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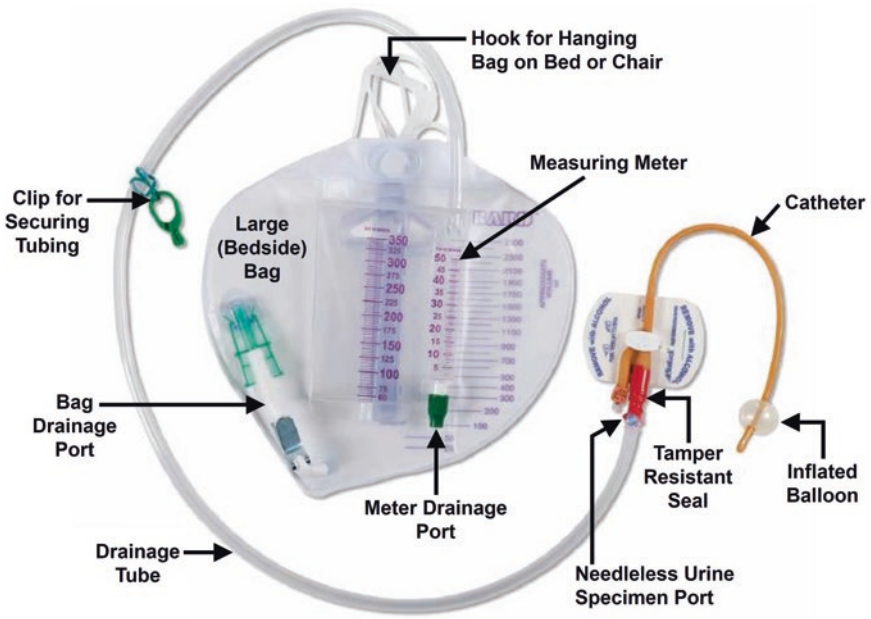


Fig. 1.1 Components of a closed sealed catheter drainage system—Courtesy of C.R. Bard, Inc, and Diane Newman

registered nurses (RNs) whereas suprapubic catheterization requires specialist involvement for insertion [5]. Both methods of indwelling catheterizations are associated with complications.

A closed sterile bladder drainage system includes a balloon-retention catheter, pre-sealed collecting system that includes a drainage tube ending in a drainage bag (see Fig. 1.1 Components of a closed IUC system). Sealed systems use a plastic covering (called a "Tamper-Resistant Seal") that seals the junction where the catheter is attached to the drainage system. They are designed to prevent inadvertent opening of the closed drainage system. However, prepackaged systems may also have the potential disadvantage of allowing only the prepackaged catheter to be inserted [6]. Maintaining a closed sealed IUC system may be impractical and unrealistic in patients managed by long-term catheterization who regularly switch from leg bags or belly bags to bedside bags, and in some patients with short-term IUCs.

Though there are many types of urinary catheters, this chapter will discuss only IUCs, those utilized for acute and/or chronic bladder drainage. Catheters used for intermittent catheterization are discussed in Chap. 2; catheters used externally for incontinence are discussed in Chap. 3; catheters and stents which are utilized in the upper urinary tract are discussed in Chap. 4; urinary drainage bags are found in Chap. 5; and urethral inserts are found in Chap. 7.

Urinary Retention

A very common indication for urinary catheter placement is urinary retention (UR). Urinary retention is the accumulation of urine in the bladder that occurs due to the inability of the bladder to completely empty (void). UR can be either acute or chronic. Acute UR may have a sudden onset and short duration (a few hours, not days). Typically, the individual cannot urinate at all, even with a full bladder. Acute UR is a potentially life-threatening condition that requires immediate emergency treatment. Chronic UR is manifested by incomplete emptying of the bladder, with or without volitional voiding, resulting in an elevated post-void residual (PVR) urine volume. It is usually not associated with pain and can be a long-lasting condition. Incomplete bladder emptying refers to the sensation or symptom that the bladder does not feel empty after voiding is finished [7]. In some cases, there are few if any symptoms or signs of UR and this is particularly relevant in the patient with impaired sensation (peripheral neuropathy secondary to chronic diabetes, spinal cord injury, etc.,) or cognitive dysfunction. Chronic UR is seen in patients with neurogenic lower urinary tract dysfunction (NLUTD) (e.g., multiple sclerosis, stroke, spinal cord injury) and those with overflow incontinence related to poor bladder contractility or bladder outlet obstruction. Typically, individuals with chronic UR can urinate, but are unable to completely empty their bladder and may be unaware they have this condition until they develop another urinary problem. See Table 1.1 for signs and symptoms of UR.

There is no standard definition of partial UR either clinically or within the research realm; therefore, the precise urinary volume that constitutes a diagnosis of UR is not available. Furthermore, the literature does not specify a specific volume above which catheterization is necessary or even recommended. Indeed, such a determination is made by individual practitioners on a case-by-case basis. For example, some patients will maintain PVRs of several hundred milliliters (mLs), but have no symptoms or related complications.

Table 1.1 Signs and symptoms potentially suggestive of urinary retention

Signs
• Urinary frequency
• Urgency
• Incontinence
• Decreased urinary stream
• Straining to void (Valsalva voiding)
• Nocturia
• Nocturnal enuresis
• Double voiding
• Dysuria
• Suprapubic/pelvic pain and discomfort
• Sensation of incomplete emptying
Symptoms:
• Distended lower abdomen/pelvis
• Pelvic mass
• Hematuria
• UTI
• Hydronephrosis
• Sepsis
Associated signs
• Prostatic enlargement in men
• Pelvic organ prolapse in women
• Fecal impaction

In such individuals, catheterization of any kind is not indicated. On the contrary, other individuals will carry a minimal PVR of less than 100 milliliter (mL), but have significant symptoms or complications (e.g., UTIs) that warrant the initiation of some type of catheterization regimen.

Prevalence

An IUC is a very commonly used indwelling device in hospitalized patients. IUCs are inserted in approximately 12–16% of adult patients and up to 25% of all patients [8]. Their use is greater in high acuity patient units, with critical care and intensive care units (ICU) having the highest. At least 8–23% of patients admitted through the emergency room receive an IUC [9–11]. Nearly 50% of surgical patients remain catheterized beyond 48 hour (h) postoperatively. Approximately 50% of medical patients do not have a clear indication for an IUC. Unfortunately, it is not uncommon for clinicians to overlook in the hospitalized patient indications for timely catheter removal which may contribute to prolonged unnecessary urinary catheterization and risk of infection (e.g., CAUTIs) or other related complications. Multiple studies show that between 21% and 55.7% of urinary catheters are placed in patients who do not have an appropriate indication and may not even need one [12].

The prevalence of urinary catheter use in residents in long-term care (LTC) facilities in the US is estimated to be 5–7% [13].

In the community, the prevalence of IUC is difficult to determine since many of the long-term IUC patients are lost to urologic follow-up and are managed by home care nurses or allied professionals. In 2007, a National Home and Hospice Care Survey reported catheter prevalence in home care setting (excluding hospice) at 9% ($n = 4683$) or 135,000 people with catheters out of the 1.5 million home care patients (http://www.cdc.gov/nchs/fastats/homehealthcare.htm).

While short-term and long-term IUC terminology exists, the length of time associated with short-term versus long-term IUCs is not standardized. Short-term catheterization has been cited to vary from 14 to 30 days; meanwhile, the exact definition for long-term IUC remains quite variable [14]. Nevertheless, many experts consider a long-term IUC to be one that is in-situ for more than 30 days.

Indications

Indwelling catheter overuse occurs when a device is in place without an appropriate indication. There are two ways of reducing IUC use: first by minimizing the initial placement of IUCs, second by reducing the duration of each catheterization. Urinary catheters have various medical indications but the most common is short-term drainage of the urinary bladder. Adequate bladder drainage is necessary for a variety of reasons including monitoring urine output for acute medical conditions and following surgical intervention; prevention of upper urinary tract deterioration, comfort at the end of life; and many other situations.

In selected patients with chronic incomplete bladder emptying, long-term IUCs may be indicated under certain circumstances. Incomplete bladder emptying may result in complications such as recurrent UTIs, sepsis, bladder stones, pain, or refractory lower urinary tract symptoms (e.g., overflow incontinence, urinary frequency, urgency, pain, etc.). For patients, where other treatments such as surgery or intermittent catheterization are either unwanted or unable to be initiated, an IUC may be an alternative. In such cases, IUCs are a treatment of last resort, only after other measures have been carefully considered and deemed inappropriate. In such individuals, the catheter should be changed approximately every 4–6 weeks. Careful surveillance of the bladder (via cystoscopy) for malignant changes and, urethral erosion due to the catheter, stones or other complications is warranted in such patients on an annual or bi-annual basis.

For some patients with upper tract deterioration, due to elevated bladder storage pressures (e.g., poor compliance from prior radiation therapy, neurogenic disease, etc.), an indwelling catheter may have a role. The indwelling catheter permits low pressure, unimpeded drainage of urine from the upper urinary tract through the bladder and then directly into a collection receptacle.

The indications for short-term versus long-term IUC differ. These indications will not be discussed in detail but it is

Table 1.2 Appropriate indications for indwelling urinary catheter

- Management of acute urinary retention or bladder outlet obstruction
  - Acute urinary retention without bladder outlet obstruction (e.g., medication-related urinary retention)
  - Acute urinary retention with bladder outlet obstruction due to non-infectious, nontraumatic diagnosis (e.g., exacerbation of benign prostatic hyperplasia)
  - Chronic urinary retention with bladder outlet obstruction preventing intermittent catheterization
- Urine output measurement in critically ill patients
  - Hourly measurement of urine volume required to provide treatment (e.g., management of hemodynamic instability, hourly titration of fluids, drips (e.g., vasopressors, inotropes), or life-supportive therapy
  - Daily (not hourly) measurement of urine volume that is required to provide treatment and cannot be assessed by other volume and urine collection strategies (acute renal failure work-up, or acute IV or oral diuretic management, IV fluid management in respiratory or heart failure)
- Single 24-h urine sample for diagnostic test that cannot be obtained by other urine collection strategies
- Reduce acute, severe pain with movement when other urine management strategies are difficult (e.g., acute unrepaired fracture, dying patient)
- Assist in healing of stage III or IV or an unstaged pressure injury or similarly severe wounds of other types that cannot be kept clear of urine despite wound care and other urinary management strategies
- Improve comfort in end-of-life care when urine collection by catheter addresses patient and family goals in a dying patient
- Perioperative use in selected surgical procedures (e.g., prolonged duration of procedure, large volume fluid infusion) and should be removed in post-anesthesia care unit
- Urologic/other surgeries (e.g., gynecologic, colorectal) performed on contiguous structures of the genitourinary tract such as bladder or urethra for which a prolonged period of drainage is necessary for healing
  - When placed just for bladder decompression/filling such catheters can usually be removed at the end of surgery or when the patient is ambulatory postoperatively
  - When used for reconstructive surgery (urethroplasty, urethral diverticulectomy, urethrovaginal fistula, vesicovaginal fistula, bladder trauma, radical prostatectomy, bladder surgery, augment/partial cystectomy/neobladder, etc.) a catheter may be needed for as long as 7–21 days for proper wound healing and adequate urinary drainage
- Patients with urinary incontinence (UI) for whom nurses find it difficult to provide skin care despite other urinary management strategies and available resources, such as lift teams and mechanical lift devices (e.g., turning causes hemodynamic or respiratory instability, strict prolonged immobility [such as in unstable spine or pelvic fractures]), strict temporary immobility after a procedure [such as after vascular catheterization], or excess weight (>300 lb) from severe edema or obesity)
- Need for intra-operative hemodynamic monitoring
- Management of hematuria associated with clots
- Management of immobilized patients (e.g., stroke, pelvic fracture)

Adapted from [8, 14, 130]

important to recognize that an IUC should be indwelling for the shortest amount of time possible. The CDC HIPAC guideline and other evidence-based clinical practice guidelines have developed criteria for appropriate (see Table 1.2)

Table 1.3 Inappropriate uses of indwelling urinary catheters

- Placement and routine use in ICU or elsewhere—without an appropriate indication
- As a substitute for nursing care of the patient with UI when nurses can turn/provide skin care with available resources, including patients with intact skin, incontinence-associated dermatitis, pressure injury stages I and II, and closed deep-tissue injury
- As a means of obtaining urine for culture or other diagnostic tests when the patient can voluntarily void and/or can provide a suitable clean-catch specimen
- For prolonged postoperative duration without appropriate indications (e.g., structural repair of urethra or contiguous structures, prolonged effect of epidural anesthesia, etc.)
- Placement to reduce risk for falls by minimizing the need to get up to urinate
- Patient or family request when no expected difficulties managing urine otherwise in non-dying patient, including during patient transport
- Patient ordered for "bed rest" without strict immobility requirement (e.g., lower-extremity cellulitis)
- Preventing UTI in patient with fecal incontinence or diarrhea or management of frequent, painful urination in patients with UTI. Fecal incontinence and diarrhea should be managed using a fecal containment device

Adapted from [8, 14, 130]

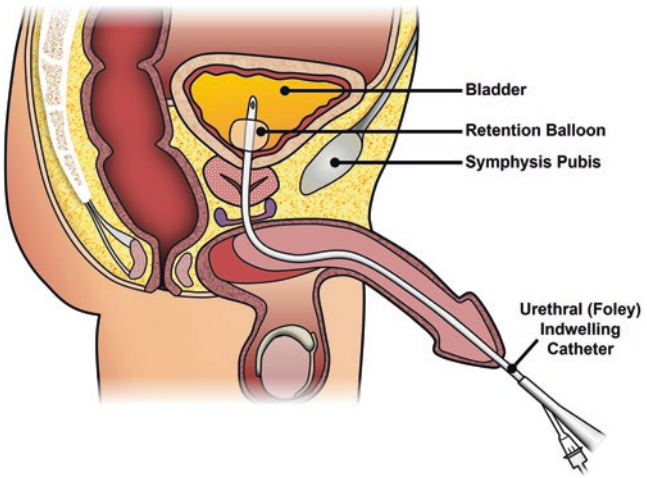


Fig. 1.2 Indwelling urethral (transurethral) catheter—Courtesy of Diane Newman

and inappropriate (see Table 1.3) IUC indications. Although these were developed primarily for the acute care setting, they have application to all care settings [8].

Characteristics of Urinary Catheters

Types

There are two routes for IUC insertion into the bladder: per urethra or transurethrally (see Fig. 1.2) or through a lower abdominal suprapubic incision (see Fig. 1.3) (often referred

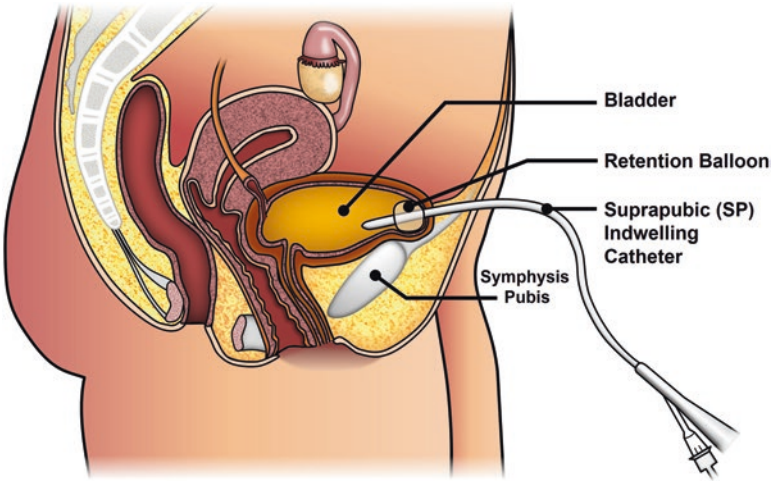


Fig. 1.3 Suprapubic catheter—Courtesy of Diane Newman

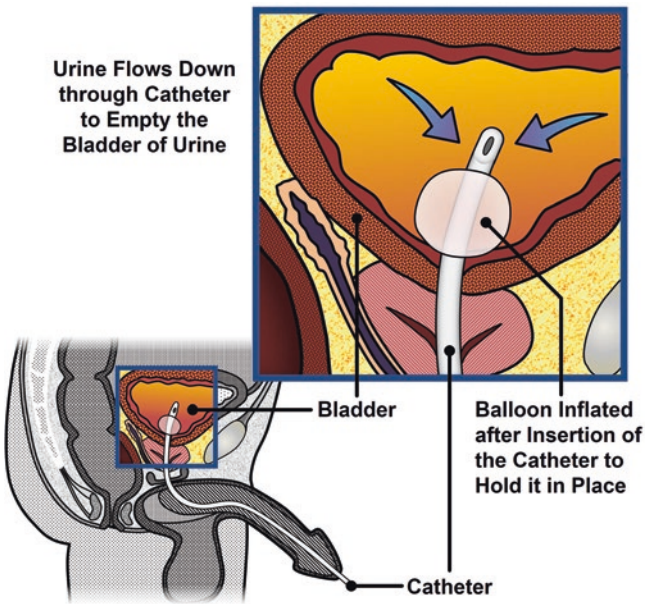


Fig. 1.4 IUC with balloon in place—Courtesy of Diane Newman

to as an "SP tube"). The most common route is transurethrally. In both sexes, the catheter is placed into the urethral meatus (opening), traverses the length of the urethra, and then enters the bladder. The return of urine from the external end of the catheter confirms proper location in the bladder. As noted previously, the IUC is held in place by a balloon located at the tip of the catheter that is inflated once the catheter is in the bladder (see Fig. 1.4). Suprapubic catheters are inserted directly into the bladder percutaneously, 2–3 centimeter (cm) above the suprapubic bone in the office, or in the operating room (see Fig. 1.5a–c. Sites of SP insertion) [15]. The entrance into the bladder through the skin is known as a cystostomy.

Materials

Catheters are made from various materials and coatings can be applied to the surface of the catheter to improve their biocompatibility, ease their insertion, and minimize infections. Catheter materials and coating can be significant factors when selecting an IUC as each have their advantages and disadvantages. Table 1.4 outlines the advantages and disadvantages for each of the different types of materials used in the manufacture of IUCs. Latex allergy is an important consideration as many urinary catheters are constructed from latex or a related material. Latex catheters are made by immersing a catheter into liquid latex. These catheters cause a latex allergy in 8–17% of medical professionals. In patients, prevalence is higher in those with spina bifida or spinal cord injury (47%). Latex allergy prevalence in the general population is 1–6%. Ideally, manufacturers should eliminate the use of latex and any other potentially anaphylactic or irritating materials in order to minimize such complications associated with urinary catheterization [16]. For patients with a latex allergy, a 100% silicone catheter could be an option, whereas a red rubber catheter could not, since it is made out of latex. Silicone catheters are extruded as a continuous tube, cut to a specific length, and the tip and opening are bonded to each end. Silicone catheters have smooth surfaces and are usually not modified, whereas latex catheters are often coated with silicone or polytetrafluoroethylene (PTFE) to help reduce friction. Silicone is a less flexible material than latex which can cause increased discomfort during placement and following insertion. In addition, silicone catheter balloons have "memory" when deflated, which leaves an uncomfortable ridge or cuff on the catheter end, resulting in pain with removal (Fig. 1.6: Deflated silicone catheter with ridge at the location of the deflated balloon). Despite these

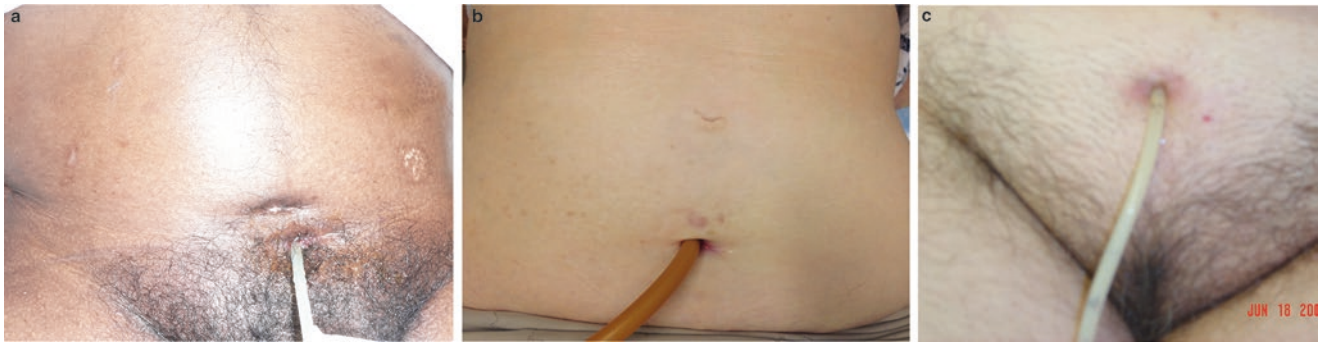


Fig. 1.5 Sites of suprapubic catheter insertion

Table 1.4 Catheter material advantages and disadvantages

Type	Advantages	Disadvantages
Latex (*red* rubber)	• High stretch ratio • High level of resilience • Extremely waterproof • Low cost • Pliable • Durable, easily processed • Most are now coated with silicone elastomer • Preferred use for dilation in men with urethral strictures • Can be modified by PTFE coatings	• Cytotoxicity potential to mucosal tissue • Absorbs fluid causing decreased lumen diameter. • Relatively higher surface friction making insertion potentially uncomfortable • Most susceptible to biofilm formation and encrustation • Contraindicated in patients with latex allergy • Not used in pediatric patients because of latex exposure
Hydrogel-coated "Lubricath" latex	• Hydrogel absorbs secretions from the urethra (hydrophilic), causing the catheter to soften and be more comfortable • Produces a slippery (lubricious) outside surface that reduces friction and protects urethra from tissue damage • Resists encrustation and bacteria colonization • Consider for long-term IUC use as may be better tolerated	• Because these are latex modified with hydrogel, allergy remains a concern
Silicone-coated latex (silicone elastomer)	• Minimum urethral irritation, allowing smooth insertion as coating is chemically bonded to the inner and outer surface of the latex catheter • Elastomer provides "elasticity" and prevents any chemical release from the latex catheter	• Coating will dissolve over time and latex hypersensitivity may still occur • Balloon may lose fluid over time • Monitor for latex allergy • Should only use short-term
Teflon-coated latex (PTFE or polytetrafluoroethylene)	• Self-lubricating • Can be autoclaved or ethylene oxide sterilized • Developed to protect the urethra against latex • Has good biological compatibility and low co-efficient of friction • Absorption of water is reduced due to the Teflon coating • Smoother than plain latex, which helps to prevent encrustation and irritation	• Because these are Teflon-coated latex catheters, allergy remains a concern • Predisposed to infection and encrustation • Toxic • Stiff
100% silicone	• Thin-walled, more rigid catheters with a wider lumen diameter that does not allow buildup of protein and mucus (biofilms) • Inert product that is clear or white in color. • Non-allergenic, non-coated • Superior resistance to kinking • May be preferable for more prolonged catheterization to reduce the risk of encrustation as there is a long lifetime between encrustations and blocking • Latex-free which allows hospitals to ensure a "latex-reduced" environment • Some patients report silicone catheters feel smoother and experience less pain with catheter insertion	• Entirely free of latex • Stiffer catheter that may be uncomfortable once inserted • May need to change catheter more frequently • Great tendency for balloon to lose fluid over time which can cause the balloon to form a crease or cuff on deflation compared to latex catheters, especially when used suprapubically. A crease or cuff can cause urethral trauma during catheter removal (see Fig. 1.6) • Catheter may "fall out" as balloon loses fluid (premature device failure)

(continued)

Table 1.4 (continued)

Type	Advantages	Disadvantages
Silver alloy/hydrogel coated (combines a thin layer of silver alloy with antiseptic hydrogel)	• Silver is an antiseptic that inhibits growth of gram-positive and gram-negative bacteria • Reduce bacterial adherence/encrustations • Minimize biofilm formation through their release of silver ions, which prevent bacteria from settling on the surface • May decrease encrustations	• More expensive than other catheters. • Effectiveness is shown only for short-term use (e.g., 2 weeks) • If CAUTI rate does not decrease after implementing a comprehensive strategy to reduce rates, consider using antiseptic-impregnated catheters
Antimicrobial/Antiseptic catheter (coated with nitrofural, minocycline, rifampin)	• May decrease symptomatic UTIs if used short-term • Clear evidence bacteriuria is decreased, but not good evidence if symptomatic UTI is decreased • Consider using to reduce bacteriuria in patients who need IUC short-term (<14 days in situ)	• More expensive than other catheters • May develop a resistance to antibiotic used for coating • Nitrofural-coated catheters are no longer available

Adapted from [14, 18, 24, 25, 131, 132]

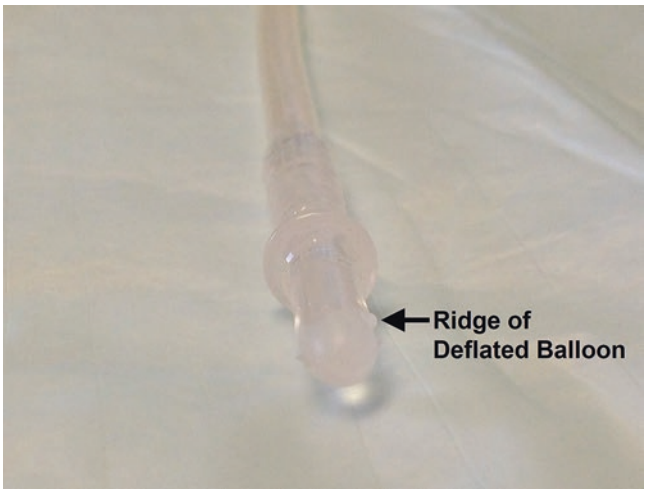


Fig. 1.6 Deflated silicone catheter with ridge at the location of the deflated balloon—Courtesy of Eric Rovner

disadvantages, silicone is the material of choice for urinary catheters [17, 18]. Silicone alone, or as a base catheter material, circumvents many of the problems faced by latex catheters. For individuals who experience recurrent UTIs, a silver alloy or antibiotic impregnated catheter may be an option as they have antimicrobial properties. Silver is an antiseptic that inhibits growth of gram-positive and gram-negative bacteria. Silver-coated catheters may reduce urinary catheter-related bacteriuria and have a low risk for generating antibiotic resistance [19–21], however, the data in support of this notion is minimal. A Cochrane group review concluded that silver-alloy coated latex catheters prevent asymptomatic bacteriuria only in patients with short-term IUCs (<14 day in-situ) [22]. At present, substantial evidence does not exist to recommend silver-alloy coated latex catheters for long-term use in the prevention of UTIs [8]. In an attempt to prevent bacterial colonization and biofilm formation, some catheters have been impregnated with antibiotics or antiseptics. Usually the outer wall and inner drainage lumen of these catheters are impregnated with an antibacterial agent (e.g., rifampin, minocycline, nitrofural), which exudes from the catheter over a period of days after insertion [23]. Antibiotic impregnated catheters, have been shown to reduce bacteriuria in hospitalized patients that have the catheters placed for less than a week [24]. But in 2012, nitrofural impregnated catheters were taken off the market. Thus, the utility of either of these two types of catheters in patients requiring long-term bladder drainage, as compared to standard (less expensive) catheters is unknown.

Designs

Catheters come in varying sizes and shapes. The vast majority of IUCs are 41–44 cm in length although specialized catheters that are longer and shorter also exist. Catheter diameter is also variable (Fig. 1.7: Varying Catheter Diameters). J.F.B Charriere, a French instrument maker, standardized a system of catheter sizing with respect to diameter. The French catheter scale, French gauge (Fr or F) or Charriere (Ch), is based on the cross-sectional diameter of the catheter in millimeters. The cross-sectional diameter of a urinary catheter is equal to three times the diameter. For example, a 30 French (Fr) catheter is 10 millimeter (mm) in diameter.

In general, urinary catheters range in diameter size from 8 Fr to 36 Fr, although some highly specialized catheters may be smaller or larger than this range. Since urethral mucosa contains elastic tissue, which will close around the catheter once inserted, the catheter chosen should be the smallest catheter size that will adequately address the indication for insertion. The routine use of large-size catheters (>16 Fr or larger) is not recommended because IUCs with larger diameters can cause more erosion of the bladder neck and urethral mucosa. They can cause stricture formation, and do not allow adequate drainage of periurethral

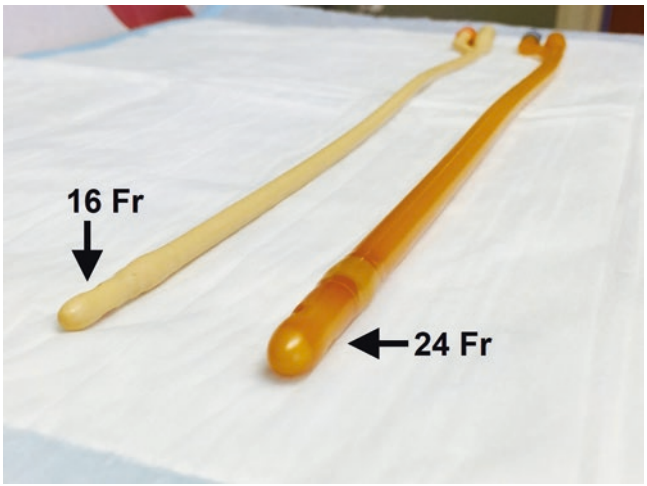


Fig. 1.7 Various sizes of catheters—Courtesy of Eric Rovner

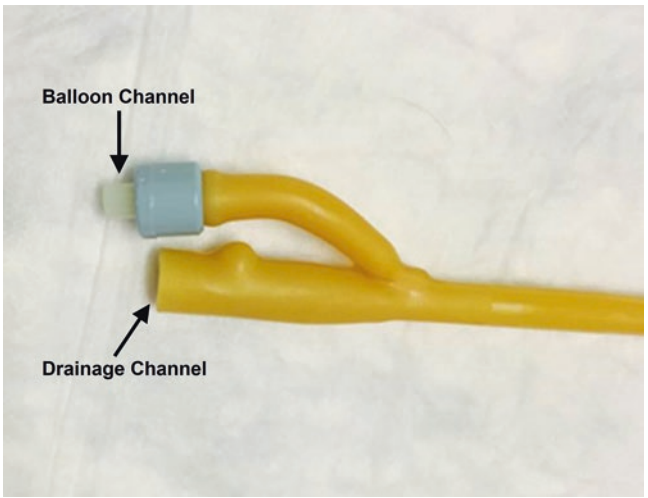


Fig. 1.8 Distal end of catheter

gland secretions, causing a buildup of secretions that may lead to irritation and infection [25]. Larger Fr sizes (e.g., 20–24 Fr) are typically used for drainage of hematuria or blood clots. The most commonly utilized indwelling urethral and suprapubic catheters range from 14 to 16 Fr in both adult females and males. These are also the standard catheters in most commercially available IUC insertion kits or trays. In adolescents, catheter size 14 Fr is often used, but for younger children, pediatric catheter sizes of 6–12 Fr are preferred.

When deciding which size catheter to use, it is important to consider the patient's gender, the purpose of placing the catheter, and the patients' anatomy. The goal of most catheterizations is to facilitate maximal drainage with minimal patient discomfort and complications. Generally, a 14 Fr is a reasonable compromise for most situations however, other clinical situations, as noted above, may require larger or smaller catheters. For example, if the catheter was placed to promote hemostasis within the urethra, a larger diameter catheter would provide some potential compression to the urethral lumen to minimize some types of bleeding. In addition, larger catheters are more likely to provide improved drainage in the setting of urinary tract debris (sediment, blood clots, stones, etc.). The British Association of Urological Surgeons Suprapubic Catheter practice guidelines [26] recommend a 16 Fr catheter as the minimum diameter catheter suitable for long-term use of a SP catheter. Larger catheters are associated with more discomfort on insertion and are less flexible resulting in relatively greater patient discomfort while in situ.

The distal end of most IUCs contain two ports (lumen/channel or dual lumen). One is a funnel shaped drainage port to allow efflux of urine once the catheter is placed and the other port is the inflation/deflation port for infusion of water into the retention balloon (Fig. 1.8: Distal end of two channel/lumen catheter). The infusion port for the balloon

Fig. 1.9 Balloon port noting catheter size (16Fr) and balloon size (10cc)

is usually labeled with the size of the balloon and the size of the catheter (see Fig. 1.9: Balloon port noting catheter and balloon size). Catheter sizes are color-coded at the balloon inflation site for easy identification (see Fig. 1.10). Certain very specialized catheters have a third port (triple lumen) which is also funnel shaped (Fig. 1.11a-d: three-way catheters). This third port allows fluid to flow into the bladder through the catheter in order to "wash" the bladder of blood and debris under certain clinical circumstances. This type of catheter is termed a three-way catheter and is used for continuous bladder irrigation or CBI, usually after some type of lower urinary tract surgery (most often transurethral resection of the prostate [TURP] or for instillation of medication). Standard intravenous tubing and an adaptor can be inserted in the third lumen to allow for infusion of irrigant solution (Fig. 1.11b). Three-way lumen catheters

Color		Size French	Size Millimeter
	Green	6	2.0
	Blue	8	2.7
	Black	10	3.3
	White	12	4.0
	Green	14	4.7
	Orange	16	5.3
	Red	18	6.0
	Yellow	20	6.7
	Purple	22	7.3
	Blue	24	8.0
	Black	26	8.7

Fig. 1.10 Color-coded catheter size chart—Courtesy of Robin Noel

can also be used to accurately measure body temperature in the bladder as the third lumen may have a built in temperature-sensing thermometer (see Fig. 1.11c, d).

In general, one should utilize the smallest size catheter that can serve the purpose needed. Larger catheters can lead to catheter obstruction and provide increased pressure at the meatus causing urethral erosion in both men and women [2] (Fig. 1.12 Beginning of a distal urethral erosion down glans, Fig. 1.13a–b Male urethral ventral erosion resulting in hypospadias, Fig. 1.14a–b Female urethral ventral erosion). Of note, there is no evidence to show smaller catheters are associated with a reduction in UTIs.

Balloon Specifics

The balloon of the catheter rests at the base of the bladder, obstructing the internal urethral orifice. Catheter retention balloons range in size from 3 cubic centiliter (cc) for

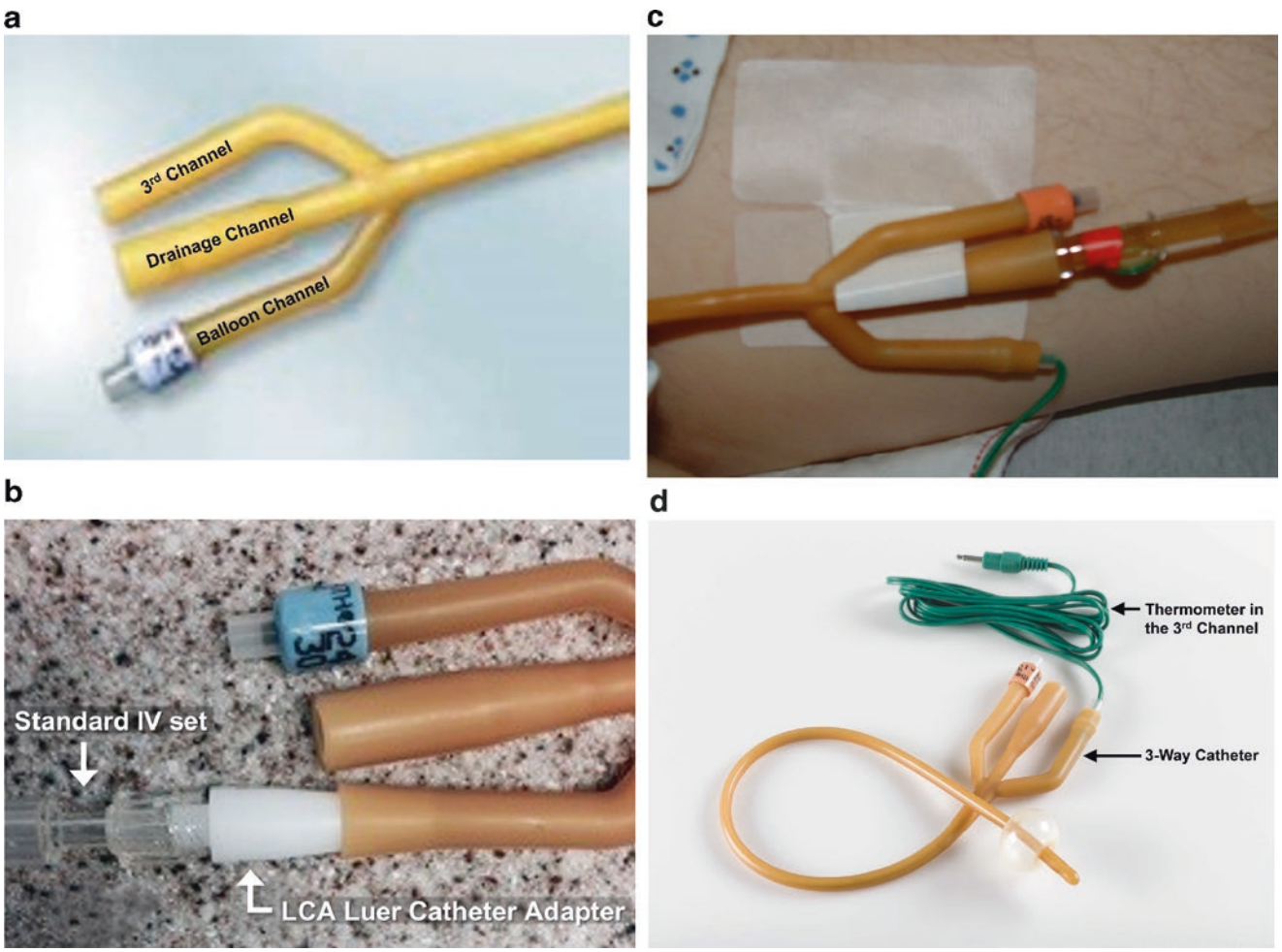


Fig. 1.11 (**a**) 3-way channel IUC. (**b**) 3-way 14Fr 30 cc balloon IUC with adapter and IV set in instillation channel. (**c**) 3-way IUC with tubing attached, anchored on the upper thigh and temperature-sensing thermometer in place. (**d**) 3-way IUC with temperature-sensing thermometer in the 3rd Channel

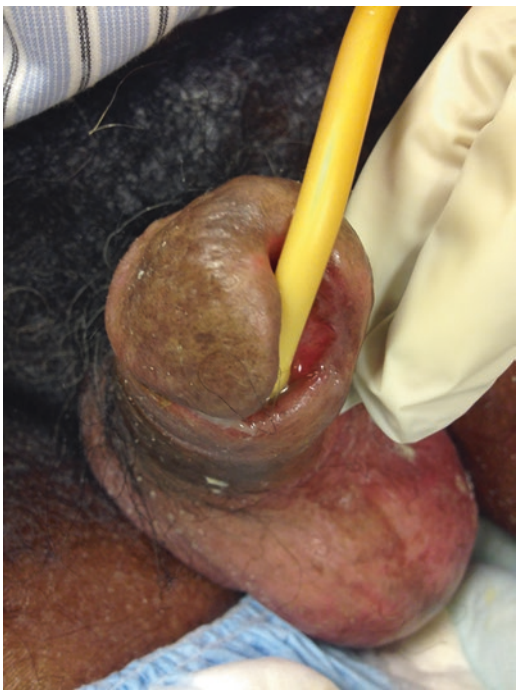


Fig. 1.12 Beginning of a distal urethral erosion down the glans—Courtesy of Diane Newman

pediatric patients to 60 cc in adults. In general, the smallest balloon size should be used whenever possible. Larger balloons (30–60 cc) are generally used to facilitate drainage or provide hemostasis when necessary, especially in the postoperative period (Fig. 1.15: Varying sizes of inflation balloons). Balloons should be filled with the manufacturer's specified amount of sterile water, which can be found printed on the inflation valve or on the catheter package. Only sterile water should be used to inflate the balloon, as saline may crystallize in the balloon port, obstructing it and, preventing balloon deflation and IUC removal [27]. The specified amount of inflation ensures a symmetrical shape and allows for the catheter to maintain position in the bladder while minimizing patient discomfort (see Fig. 1.16 Comparison between instillation of 5 mL versus 10 mL). Over inflation of the balloon can result in balloon rupture, as well as patient discomfort, and may lead to uneven inflation causing the catheter tip to rest against the bladder wall and resulting in irritation and spasm. Several catheter materials have been found to lose water from the inflated balloon over time with 100% of silicone catheters losing as much as 50% of their volume within 3 weeks [28]. The surface area, appearance, and diameter of the balloon change following deflation.

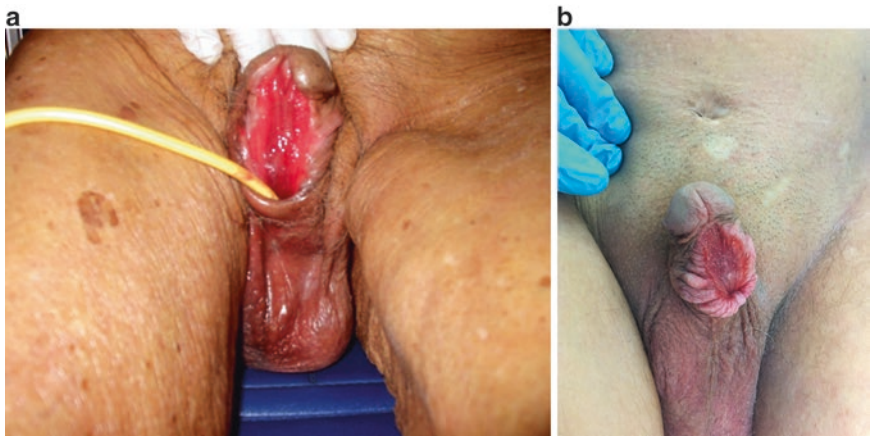


Fig. 1.13 (**a, b**) Ventral urethral erosion in a male resulting in traumatic hypospadias. The ventral surface of the penis is eroded almost down to the level of the scrotum exposing the length of the penile urethra

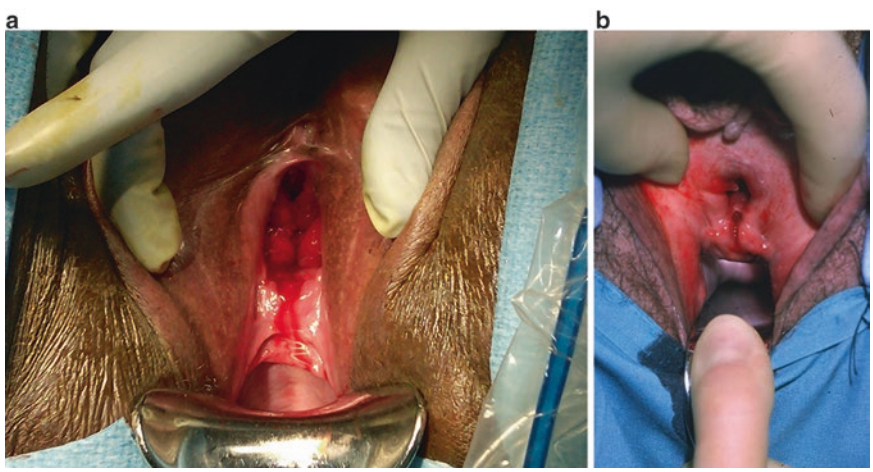


Fig. 1.14 (**a**, **b**) Ventral urethral erosion in a female resulting in a traumatic hypospadias. The urethral meatus is widely patulous

Removing the water causes the balloon to collapse and deform, which can lead to balloon creases or ridges as seen in Fig 1.6. The balloon may not slide smoothly during removal in that case, causing patient discomfort [29, 30].

There is commercially available catheter with dual or two balloons at the end of the catheter (Poiesis Duette Dual-Balloon catheter). The balloon at the tip is intended to reduce the risk of trauma to the urothelium. The drainage eyes perforate a short section of catheter between the two balloons, and the proximal balloon of which serves as the retention device. One disadvantage of the dual balloon is that it may trap more urine in the bladder at the end of drainage, increasing the risk of bladder infection. There is little information on clinical use of dual balloon IUCs.

The balloon channel incorporates a valve to prevent the sterile water from escaping when the syringe is detached.

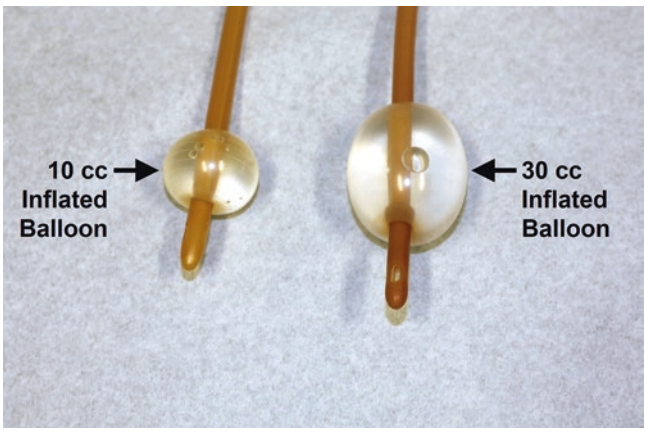


Fig. 1.15 Catheter balloons inflated—Courtesy of Eric Rovner

To remove a catheter, one must first deflate the retaining balloon by withdrawing the water from it with a Luer Lock syringe. This opens the valve in the inflation connector when it is attached.

Occasionally, the inflation balloon of an IUC will not deflate, thereby preventing removal. This can occur for various reasons, including debris in the inflation channel or balloon, a faulty syringe or catheter, the kinking of the catheter or other factors [31]. This situation requires careful assessment of the causative factors. Removing a catheter with an inflated balloon is not medically appropriate as it can cause significant urethral trauma. The balloon must be deflated prior to removal. Maneuvers to deflate the recalcitrant catheter balloon are found in Table 1.5.

Catheter Tips and Eyelets

The catheter tip extends beyond the balloon at the end of the catheter. There are 1 or 2 eye-holes, or eyelets, also termed drainage holes (see Fig. 1.17), cut into the tube adjacent to the tip to allow urine to drain. Smooth eyelet surfaces are important as rough surfaces encourage the deposition of bacterial biofilm. Sharp edges to the drainage eyes can cause bleeding from the urethral lining when introducing or withdrawing the catheter. Different catheter tips are available to allow for the least traumatic insertion and maximal drainage. These are listed in Table 1.6. For example, Coudé tip (pronounced "coo-DAY") or curved-tip catheters, which have a 45° curve over the terminal 2 cm of the tip, can be used to ease catheter placement in a man with an enlarged prostate, urethral stricture, or false

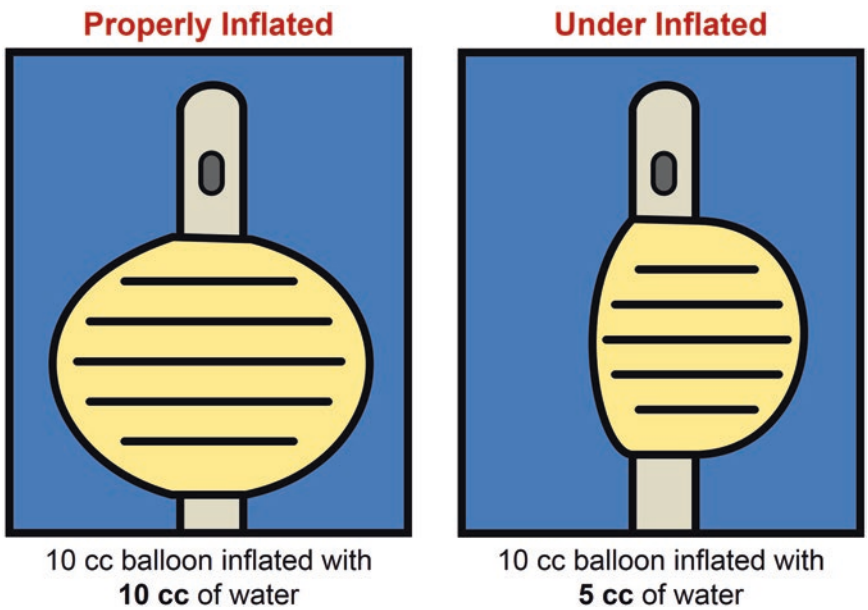


Fig. 1.16 Symmetrically shaped properly inflated balloon and improperly inflated balloon—Courtesy of C.R. Bard, Inc.

Table 1.5 Steps for IUC Balloon deflation: simple and complicated [29]

Insert a 10 cc Luer Lock syringe at the balloon lumen port and gently aspirate the fluid, which will deflate the indwelling balloon. The volume may be < 10 ccs. If there is concern that all fluid has not been aspirated, remove the syringe, squirt out all aspirated fluid and re-attach and draw back again until no fluid is seen coming out.

- Avoid forcefully retracting the plunger of the attached syringe as a vacuum may be created causing the balloon channel inside the catheter to collapse and seal itself

Initial solutions for a balloon that will not deflate, no fluid is aspirated

1. Re-engage and reposition the Luer Lock syringe. If not fully and properly engaged, the balloon will not deflate
2. Stretch or milk the catheter in hopes of dislodging debris in the deflation channel
3. Try wiggling and turning the catheter while gently pulling the plunger
4. Instill 1–2 mL of additional sterile water into the inflation channel to dislodge debris
   - Be careful to not overinflate and "pop" the balloon as a burst balloon results in balloon fragmentation, patient discomfort and likely will require cystoscopy to remove the resulting residual balloon pieces in the bladder
5. Try a different/new syringe as syringe may be faulty
6. Do not cut the catheter or balloon inflation valve as this rarely is effective and results in a compromised catheter, which is even more difficult to remove
7. Check if patient is constipated as hard stool can cause pressure on the urethra preventing balloon deflation

Invasive techniques to deflate the balloon

1. Pass a very thin long guidewire needle in the balloon channel until it touches the balloon. Do not try to puncture the balloon. If there is any obstruction in the inflation channel, the balloon will be deflated spontaneously or the removal of the wire will induce deflation
2. Using ultrasound, locate the balloon inside the bladder and puncture it suprapubically
3. Use a finger puncture set (like the ones used for prostate biopsies) to locate and puncture the balloon through the rectum (in the male) or the vagina (in the female)
4. Overinflate the balloon past its maximum, so it will burst

Any maneuvers that result in balloon rupture may be associated with retained fragments of the balloon within the bladder that requires subsequent cystoscopy in order to retrieve the balloon pieces

Table 1.6 Various types of catheter tips and indications for use

Type	Tip description	Uses
Straight (round) tip	Standard	Suprapubic tube or Simple catheter placement
Coudé or Tiemann tip	Distal 2–3 cm of the catheter is curved at a 45° angle	Slightly curved tip allows for easier insertion in cases of prostatic obstruction due to BPH, or in some cases of urethral stricture or false passage
Whistle tip	Open-ended tip with lateral drainage holes and larger lumen	Is often used to enhance drainage of debris or for catheter irrigation
Roberts tip	Multiple drainage holes both proximal and distal to the balloon	To enhance drainage of debris, has 2–6 openings, thus if one opening clogs, then the other openings allow for drainage
Council tip	Drainage hole is at the very tip of the catheter	Allow for utilization of guidewire in order to place or replace catheter in difficult cases
Malecot	Self-retaining non-balloon tipped catheter. The catheter is retained by expansion of 4 winged struts in the shape of a mushroom which deploy after placement	Allow for drainage following renal or bladder surgeries. Wings provide proper catheter placement and retention, as well as drainage. Rarely if ever used for urethral drainage
DePezzer	Similar to a Malecot catheter with a bulbous tip instead of four wings	Used in similar circumstances as Malecot
Couvelaire	Tip has very large drainage holes on opposite sides of the catheter	Utilized for post-surgical cases associated with hematuria or debris. Also has a 30 cc balloon, which can be utilized to tamponade bleeding

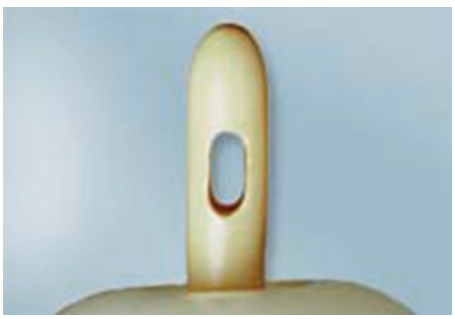


Fig. 1.17 Eyelet at catheter tip

passage. Such a Coudé-tipped catheter allows easier passage through the "J-shaped" curvature of the male urethra, and allows for smooth insertion through the prostate and bladder neck (see Fig. 1.18a–b). For insertion, the Coudé tip catheter is angled upward (toward the 12 o'clock position) at the tip (see Fig. 1.19).

Council tip catheters, which have an eyelet at the very tip of the catheter, allow for placement in difficult cases where the catheter is required to be placed over a wire. The council tip catheter is passed over a previously placed guidewire traversing the entire urethra that was temporarily put in the bladder via direct visualization with cystoscopy (Fig. 1.20 catheter tips). If one does not have a council tip catheter, a standard IUC can be converted to a council tip with a council tip catheter maker (Fig. 1.21 Council tip catheter maker).

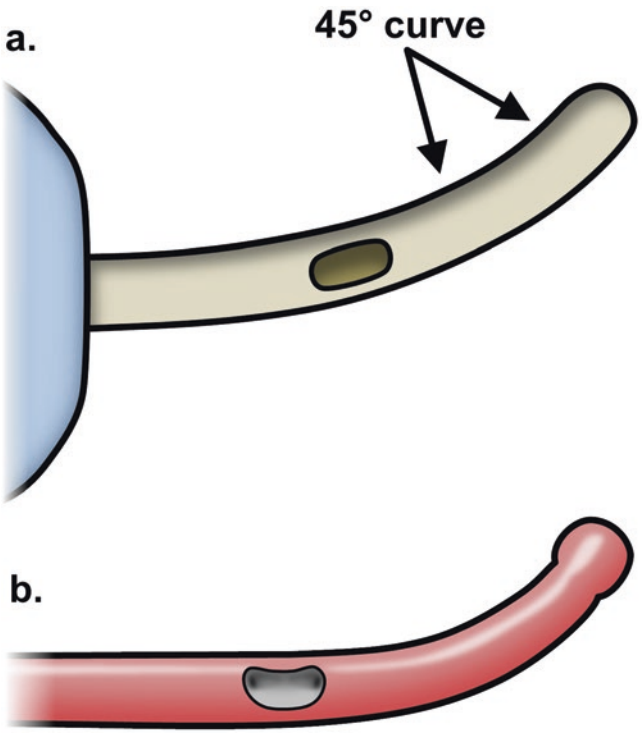


Fig. 1.18 (**a**) Angle of a coudé tip catheter. (**b**) Coudé tip red rubber latex catheter—Courtesy of Diane Newman

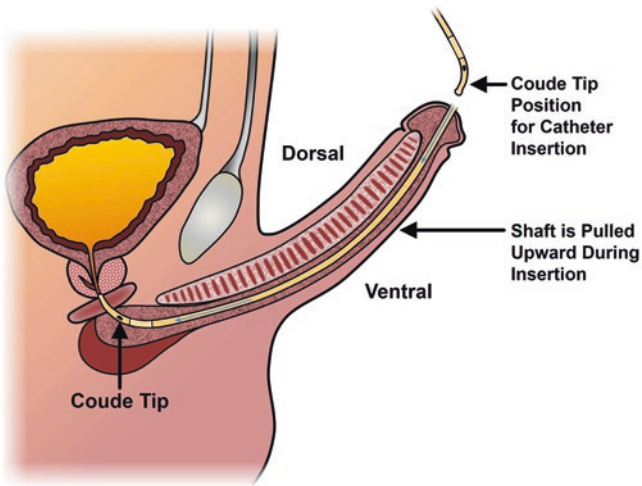


Fig. 1.19 Proper position of the penis for insertion of a Coudé tip catheter—Courtesy of Diane Newman

Catheterization Techniques/Procedure

Urinary catheter placement is a skill acquired by many clinicians during training. The importance of performing this seemingly simple task correctly cannot be overemphasized. Patient safety and comfort should be maximized at all times. Many patients are anxious regarding catheter placement. Patients should be counseled regarding the indication for catheter placement and reassured regarding comfort, duration of catheterization and removal. Each step of the catheterization should be explained to the patient prior to or during the procedure. Appendix 1 is a guide to routine transurethral catheterization developed by the Society of Urologic Nurses and Associates. Figure 1.22 displays a closed system indwelling catheter tray that contains all the supplies necessary for aseptic insertion of an IUC. Catheter trays have recently been developed that contain a packet for perineal care pre-catheterization with instructions (See Fig. 1.23).

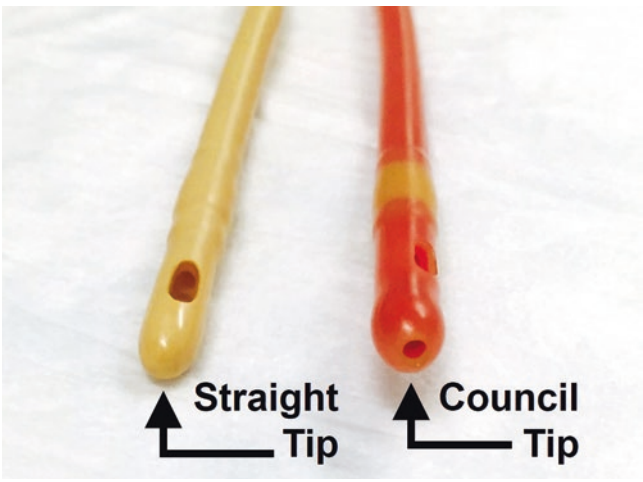


Fig. 1.20 Council tip next to straight cath tip—Courtesy of Eric Rovner

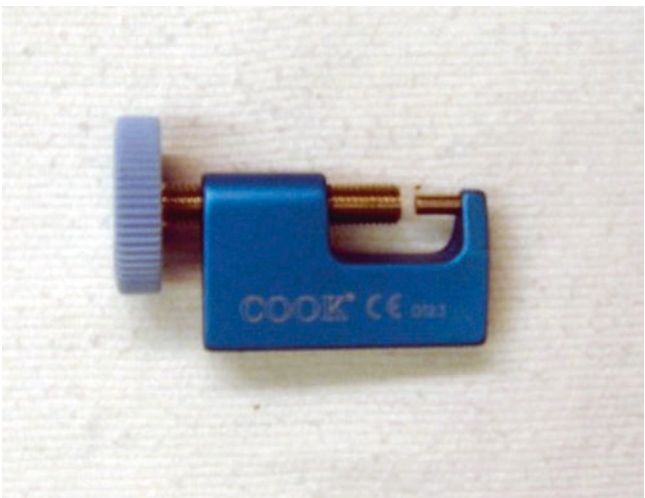


Fig. 1.21 Council tip maker—Courtesy of Eric Rovner

Positioning for Catheterization

Transurethral

There are significant differences in the anatomy and the catheterization procedure between males and females. As

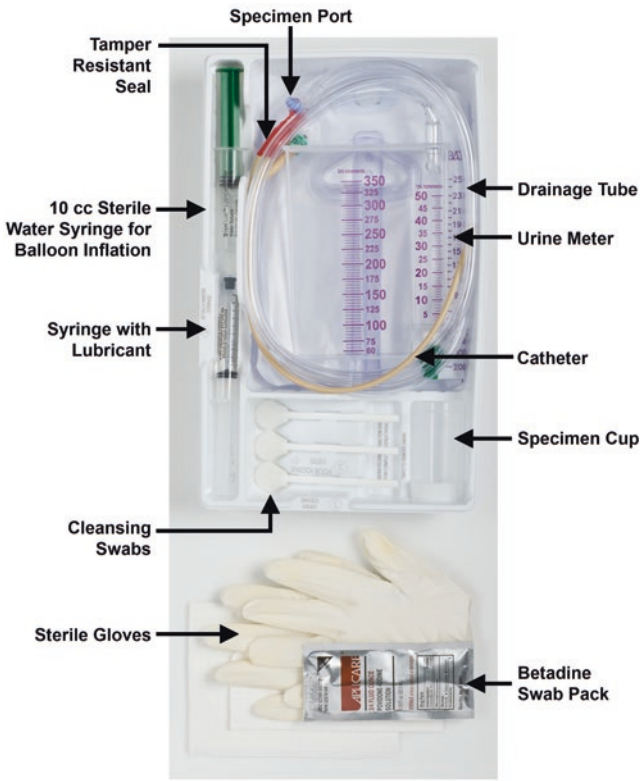


Fig. 1.22 SureStep closed IUC tray system—Courtesy of CR Bard

Fig. 1.23 Instructions and packet for periurethral cleansing packet on top of the sterile SureStep closed IUC tray system—Courtesy of CR Bard

noted previously, the female urethra is considerably shorter than the male urethra and is much less likely to have anatomic obstruction. The length of the female urethra is only 3–4 cm compared to 15–20 cm or longer in the male. The lumen of the female urethra is almost always collapsed throughout the day, and only expands and dilates during voiding when fluid is passing through it or if a catheter is inserted. Due to different anatomy and urethral lengths in men and women, different maneuvers can be used to facilitate insertion of an IUC.

The female urethra is lined proximally with transitional epithelium with squamous epithelium nearer the meatus. The epithelium is flat and ribbon-like. The lamina propria lies under the epithelium and contains a rich vascular network of blood vessels that is influenced by circulating estrogens, which makes it elastic and able to stretch. It is this ability to stretch that allows the catheter to pass through the urethra. Like the female urethra, the male urethra is lined with transitional epithelium proximally, apart from a small area of squamous epithelium close to the urethral meatus (see Fig. 1.24). Directly below the epithelium lies a thin layer of tissue rich in blood vessels but relatively inelastic. Many blood vessels from the corpus spongiosum end just below the mucosa, explaining the tendency to bleed with mild luminal trauma. Injury to the epithelium also provides an entry port for bacteria, which are readily transported via the corpus spongiosum to the blood. Scar tissue is easily formed as a result of trauma to the urethral lining resulting in urethral stricture formation.

In females, urethral catheter placement is generally simple, straightforward, and uncomplicated. Perhaps the most challenging aspect of female urethral catheterization is the localization of the urethral meatus in an obese patient. Urethral obstruction due to stricture is exceedingly rare in females. In addition, the short female urethral length permits ease in catheterization. Women should be placed in the supine or lithotomy position with knees separated to reduce fecal contamination [32]. The female meatus is found in the midline just below the clitoris and above the hymenal ring (see Fig. 1.25). Gentle retraction of the labia majora cephalad and laterally will expose the meatus even in the most obese patient who may have a slightly receded urethra. As noted, obese patients with a large pannus or patients with poor hip and leg mobility, may present a catheterization challenge. The use of leg or gluteal lifts such as that shown in Fig. 1.26 can make this procedure easier. Also, in such situations, a two-person catheterization team, one individual to hold the patient in position and/or to assist with the equipment, and the other to actually perform the catheterization can greatly facilitate the procedure.

In the male, urethral catheterization can sometimes be challenging. The male urethra is much longer (15–25 cm) than the female urethra and has a curved course (sometimes called a "J" curve) as it descends in its last 4–5 cm proximally through

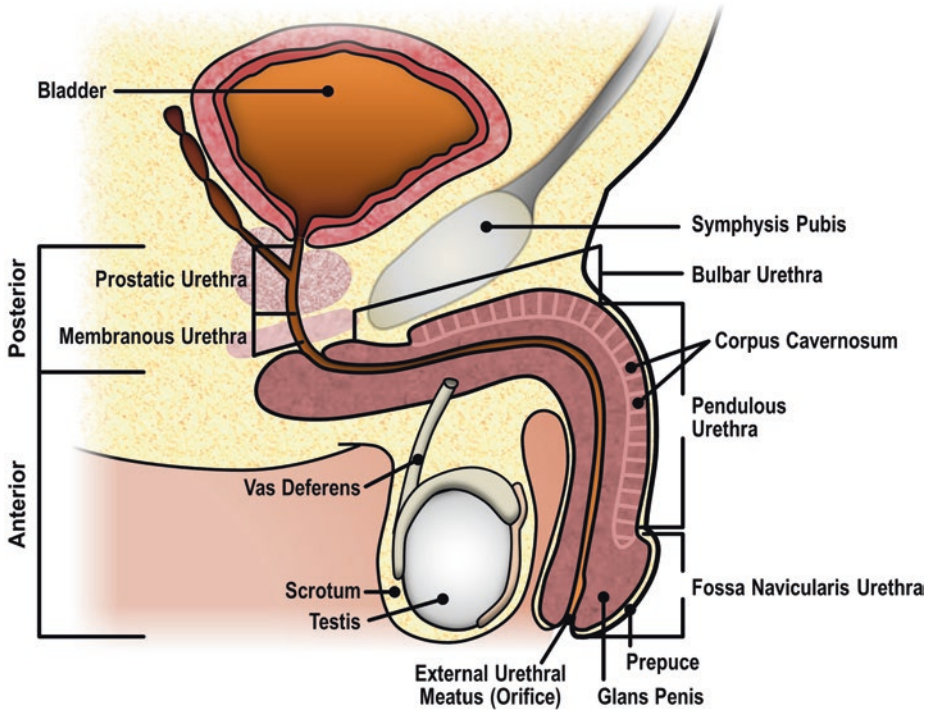


Fig. 1.24 Male urethra—Courtesy of Diane Newman

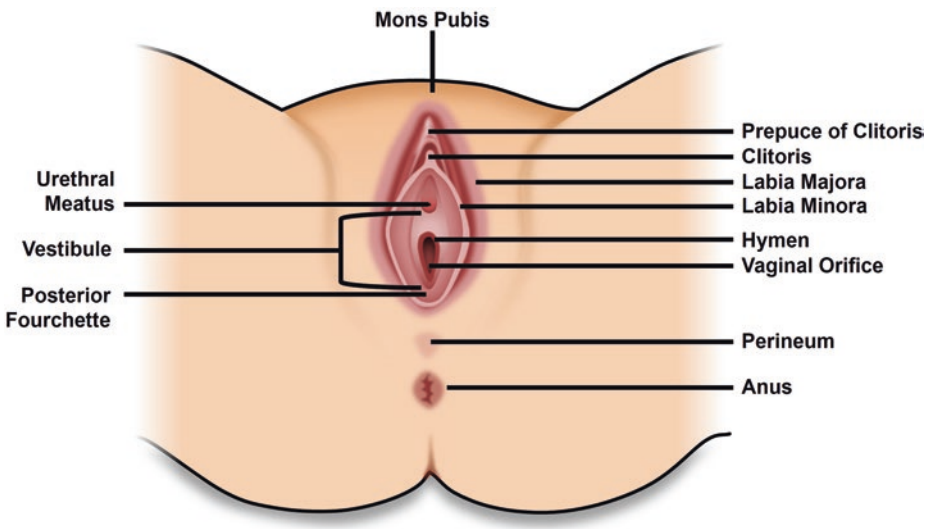


Fig. 1.25 External female genitalia—Courtesy of Diane Newman

the urogenital diaphragm and prostate (see Fig. 1.24). The male urethra may be obstructed by a stricture (narrowing due to fibrosis and scarring) or an enlarged prostate making catheterization difficult. Catheterization in males is facilitated in the supine position. The urethra can be straightened by stretching the penis distally. If the patient has an enlarged prostate, a Coudé tip catheter may be utilized and the angled catheter tip should point cephalad during the insertion.

Any difficulty in catheterization of a male or a female should mandate consultation with a specialist (urologist or

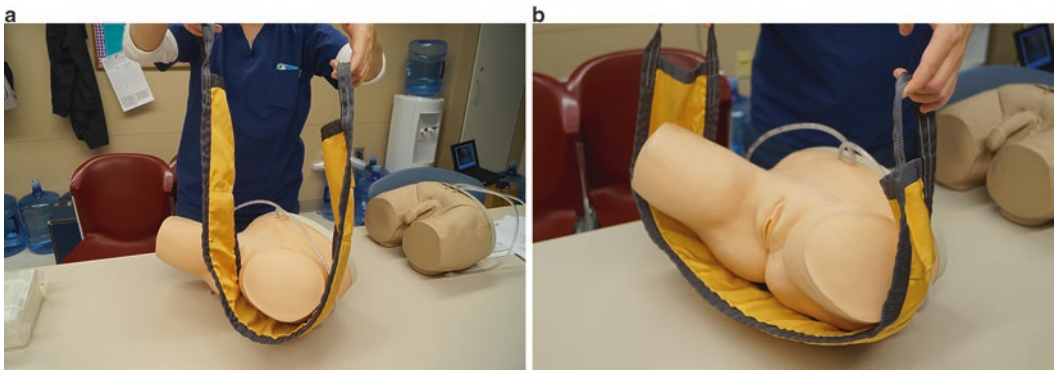


Fig. 1.26 (**a**) Leg and (**b**) pelvic lifts to improve meatal visualization during catheterization—Courtesy of Diane Newman

urology nurse) early in the process before irreversible damage is done to the urethra. Table 1.7 provides several maneuvers for difficult catheterization in male and female patients.

Suprapubic (SP) Catheterization Tubes

SP tubes are used either for short-term postoperative bladder drainage following gynecologic or urologic procedures, or long-term catheterization in which other methods of management (intermittent catheterization, urinary diversion, etc.) are either contraindicated (e.g., sacral pressure injury) or otherwise impractical. Lavelle [33] accessed the quality of life of 128 patients with an SP catheter (54 females, 35 males). They were carefully selected patients with NLUTD who had failed other options. Over 80% considered the SP catheter to have improved their quality of life around bladder management. Table 1.8 outlines the advantages and disadvantages of suprapubic catheters. Suprapubic catheters are usually inserted during an outpatient surgical procedure. These catheters should be placed with extreme caution in all individuals, but especially in those with relevant prior lower abdominal or pelvic surgery, due to the possibility of bowel adhesions interposed between the skin incision and the bladder, resulting in the increased risk of bowel injury. Additional risks of SP tube in placement include: misplacement of the catheter, bleeding, and incisional hernia. Unrecognized bowel injury is a catastrophic and potentially fatal risk of SP tube placement. Once the SP tube is placed in the operating room under general or regional anesthesia, an epithelialized tract forms over the ensuing 4–6 weeks from the abdominal skin all the way to the bladder. Such a mature epithelialized tract allows subsequent simple removal and replacement of the SP tube without the need for anesthesia or guidewires. A SP catheter does not require sutures to hold the tube in place as it is secured in place by virtue of the inflated retention balloon, similar to an intraurethral IUC. Table 1.9 provides steps for changing a SP catheter.

Catheter Changing Schedule

The optimal interval to change IUCs is not well defined. The time to change can be based on clinical indications such as infection, obstruction, or when the closed system is compromised [8]. According to a Cochrane review by Cooper [34], found insufficient evidence to support the conclusion that the presence of bacteria in urine was reduced when catheters were replaced monthly (with no clinical reason to do so) compared to when catheters were replaced only when a clinical reason existed. However, current clinical practice is to change/replace chronic IUCs with a new catheter system every 4–6 weeks to minimize stone formation, biofilm development, and to examine the tube entry site for infection, erythema, or skin breakdown.

Lubrication

Urinary catheters must be lubricated prior to insertion. Lubrication reduces the risk of urethral trauma and pain on catheter insertion, and reduces discomfort and friction, which, in turn, may reduce infection. Protecting the sensitive urothelium from trauma with an unbroken film of lubricant can reduce damage to the urethra. It is recommended that clinicians use a suitable lubricant from a single-use container when inserting urinary catheters to minimize the risk of infection and trauma to the urethra.

Table 1.7 Procedures for performing difficult catheterization

Procedure for difficult male catheterization

1. Lubricating the urethra prior to attempted catheterization can alleviate pain and decrease sphincter contraction that creates resistance to the catheter placement
   - Gently and slowly instill 10–20 mL, of anesthetic gel (2% lidocaine) or water soluble gel into the urethra. The average male urethra volume is 20 mL
   - Can use a mixture of 10 mL plain lubricating jelly with 10 mL of 2% lidocaine injected together into the urethra. This makes the mixture longer lasting as lidocaine gel dries out quickly
2. If uncircumcised, retract the foreskin to prep the glans; use a gloved hand to hold the penis still. If penile edema or a buried penis is present, minimize edema by wrapping penis with gauze and apply an elastic compression dressing for 20 min. Expose a buried penis by having an assistant press down firmly around the base of penis
3. Hold penis at 45–90 degree angle to straighten urethra and to eliminate the pendulous curvature of the penis
4. Start with a 16 Fr or 18 Fr catheter. An adult male external meatus should allow a catheter as large as a 24 Fr to pass as the smallest part of the urethra has a caliber of 32 Fr or greater
5. Gently and slowly insert the catheter with your dominant hand, concentrate on your fingers feeling the catheter as it inserts. The bulbo-membranous urethra is the most likely segment to traumatize
6. Encourage patient to take deep breaths and exhale slowly as this helps to relax the sphincter and urethra. The patient may also be instructed to attempt to void without straining as this relaxes the membranous urethra
7. Instruct patient to keep buttocks on the bed and avoid straining while the catheter is being placed
8. If resistance is met at the external sphincter (membranous urethra), the patient should be instructed to attempt to void without straining. This will relax the sphincter
9. Proper position of the catheter is determined by urine return from the drainage port. Advance the catheter an additional 1–2 cm. This maneuver ensures that the balloon inflates in the bladder and not in the urethra
10. If balloon is difficult to inflate or the patient complains of pain with inflation, deflate balloon fully and reposition catheter
11. If unable to pass 16 Fr catheter, switch to larger catheter or an 18 Fr Coudé tip IUC, curved tip pointing up toward the head of the patient (12 o'clock position) during insertion (see Fig. 1.19).

Procedure for difficult female catheterization

1. Position with knees flexed and legs relaxed to opposite sides (frog position) if possible to improve visualization. To further improve visualization, elevation of the pelvis and legs is helpful. Consider use of leg lifts, perineal lift or upside down fracture pan under the buttocks to lift perineum
2. A portable light is recommended to optimize vision
3. Multiple assistants or a speculum can assist with retracting the labia anteriorly and cephalad to expose the meatus
4. In obese patients, additional personnel may be needed to assist with lifting pannus up or spreading labia as meatus may be difficult to visualize
5. Use one gloved hand to prep the urethral meatus in a pubis-toward-anus direction; hold the labia apart with the other gloved hand
6. Lubricate catheter only. Can inject anesthetic gel, but will make vulva slippery, increasing difficulty with catheterization
7. If unable to see urethral meatus:
   - Clean area with betadine and look for a wink or crevice that indicates the meatus
   - Use finger and palpate superior aspect of vagina, push up and pull forward on urethra
   - If catheter is incorrectly inserted in the vagina, leave catheter in place and attempt re-catheterization using a new sterile catheter insertion tray
8. If meatus is receded back into the anterior vaginal wall, or in an obese woman, where visualization of the genitalia is a problem:
   - Consider using a Coudé tip catheter
   - Place a finger against the anterior vaginal wall, press up into the urethra and guide the catheter insertion
   - Place tip of catheter just under clitoris and slide catheter down, pressing against the vaginal tissue at approximately a 30-degree angle pointing up. Slide until dimple of meatus is located

Adapted from Leanne Schimke MSN, CRNP, CUNP

Table 1.8 Advantages and disadvantages of a suprapubic catheter

Advantages	Disadvantages
• Absence of urethral pain • Absence of the risk of urethral erosion (traumatic hypospadias) • No urethral trauma during placement and removal • Reduced risk of fecal contamination, thus reducing incidence of CAUTIs • Access to the catheter site is easier for cleansing (as compared to urethral catheters) • Easier removal and replacement in patients with decreased mobility or wheelchair bound • May provide greater sexual freedom • Allows the facilitation of trials of voiding after major surgery. The drainage tube can be clamped to allow urethral voiding and released to check if the bladder is emptying completely.	• Invasiveness of placement • Need for bladder neck closure to prevent urethral leakage in patients with incompetent urethras • May be inappropriate in obese patients, because the catheter can become trapped in abdominal skin folds • Risk of bowel injury and bleeding with placement • Sexual intercourse may not be straightforward • If the catheter becomes dislodged, a new catheter must be inserted immediately as the SP tube site can begin to close within a few minutes if insertion is delayed. Especially a concern if initial insertion is recent.

Many clinicians, especially urology specialists, advocate use of an anesthetic gel (lidocaine gel 2%) prior to catheterization, particularly in male patients. This lubricant serves three important purposes: (1) it provides local anesthesia, (2) promotes pelvic muscle relaxation, and (3) in men, helps to "open" the urethral lumen when the lubricant is held in the urethra using mild compression at the fossa navicularis (just below the glans penis) (see Fig. 1.24). Lidocaine can cause

Table 1.9 Steps for changing a suprapubic catheter

Formation of a well-established SP tract takes at least 4–6 weeks to develop completely. The first postoperative SP change should be done by a urologist or qualified health care professional and should be deferred for at least 4–6 weeks after catheter insertion to allow the catheter tract to be established. Once the tract is established and optimal catheter size achieved, a qualified professional (e.g. RN) can do subsequent changes. SP catheters are usually changed every 3–6 weeks
Equipment • A 16 Fr size catheter, with a 10 cc balloon (instilled with 10mLs of sterile water), is most commonly used • Sterile catheter insertion tray/system • Can increase by one catheter size with each change until optimal size for drainage
Procedure 1. Lay patient in supine position or as comfortable as possible 2. Place pad under SP tube and remove dressing if present 3. Assess insertion site for redness or drainage and clean around cystostomy site with chlorhexidine gluconate or betadine 4. Fill the bladder through the existing SP tube with at least 100 cc saline or equivalent fluid 5. Deflate the balloon and remove existing catheter slowly at steady rate. May experience some resistance as the detrusor and rectal muscles are stimulated or if cuffing from the balloon or encrustation is present. Fluid will flow from the empty SP tube tract maintaining a distended lumen 6. Insert the new sterile catheter for exchange through the tract. Initially, the fluid will stop flowing from the tract. Advance catheter until fluid starts to return from the catheter and then advance an additional 1–2 cm a. Catheter insertion should be performed immediately after removal of previous catheter to prevent closure of the cystostomy site 7. Inflate balloon slowly with 10 mL of sterile water. Only 10 mL balloon catheters should be used. If the patient experiences pain, immediately deflate and reposition the catheter a. There is a risk that the catheter tip will have passed into the urethra so inflate the balloon carefully b. If the patient reports discomfort or resistance to gentle inflation, urethral passage should be suspected and the catheter withdrawn and reinserted. c. Make a visual check to ensure that the catheter tip and balloon have not emerged from the urethra 8. Gently pull back the catheter with the inflated balloon until the balloon meets the anterior bladder wall as the catheter is gently withdrawn. This will ensure that the catheter is mobile within the bladder a. If fluid leaks around the SP tube, the catheter may not be fully inserted into the bladder 9. Attach to drainage bag or catheter valve 10. Anchor catheter by securing tubing to abdominal wall and reapply dressing, if desired (see Fig. 1.27b) 11. Excessive granulation tissue around the SP site can be cauterized with silver nitrate sticks to prevent bleeding

Source: [14]

possible side effects so it should be used with caution in patients who have a history of heart block or symptoms of hypotension and bradycardia. The onset of action and absorption of lidocaine in the urethra is not immediate; therefore, many clinicians leave it in situ for 10 to 15 minutes for it to achieve its favorable effects. Inadequate anesthesia can occur when insufficient time has elapsed or the gel has been applied directly to the catheter rather than inserted into the urethra [35].

Inserting a catheter into a woman with severe pelvic organ prolapse (beyond the introitus) or atrophic vaginitis (now referred to as Genitourinary Syndrome of Menopause) occasionally proves difficult. In a woman with prolapse, it's best to gently invert the protruding prolapse before identifying the urethral meatus. When treating a woman with severe atrophic vaginitis, it is sometimes helpful to inject 5 mL of 2% lidocaine gel into the urethra, and to use a Coudé-tip 14-Fr. catheter to locate the meatus, which may be partly obscured.

Catheter Securement

Although there is scant evidence to support different methods of catheter securement, practical knowledge supports some sort of securement or "anchoring." Five main indications are commonly cited for securing an IUC:

1. To obtain pressure to tamponade postoperative bleeding in those in whom this is needed;
2. To prevent mechanical trauma to the urethra (e.g., meatal erosion, urethral irritation, tearing and damage, hypospadias at the urethral meatus, pressure ulceration at the pendulous male urethra);
3. To prevent catheter dislodgement [29];
4. To avoid excessive tension on the catheter leading to bladder neck trauma; and
5. To protect surgical repair of the urinary tract [36].

A well-supported catheter can prevent many catheter-associated complications, as well as inadvertent dis- lodgement, which in itself is a cause of bladder neck and urethral trauma. In addition, proper catheter securement means increased comfort for the patient.

Even though no available evidence exists to support a reduction in infections due to securing, patients whose catheters are secured likely experience increases in comfort with less bladder neck irritation or inadvertent catheter removal in patients whose catheters are secured. Urology nurses will attest to this experience, as many unanchored patients arrive in the office with the catheter and bag "dangling" from the urethra, causing undue weight and risk of pressure necrosis on the meatus.

Although stabilization or securement cannot prevent all complications associated with a urinary catheter, the value of this practice is exemplified by its inclusion as a category 1 recommendation (i.e., strongly recommended for adoption) in CDC Guidelines for Prevention of Catheter-Associated

Urinary Tract Infections [8]. However, the best method of stabilization has not been well defined. Several best-practice models in the nursing literature recommend that the catheter be secured or anchored to the upper thigh in women and upper thigh or abdomen in men [29, 37–39].

There are various types of securement/anchor devices: a non-adhesive elastic leg band with Velcro™ closures to secure catheter (see Fig. 1.27a), a non-adhesive elastic waist band with Velcro™ closures for securement of a SP tube (see Fig. 1.27b), an adhesive patch (see Fig. 1.27c) and a manufactured plate with adhesive backing and a catheter attachment device (see Fig 1.27d). When correctly utilized to secure a bladder catheter in place, these catheter anchors should limit the "to and-fro" movement of the urethral catheter [40]. Although securement of IUCs is recommended by the CDC [8] (http://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf) as well as the Society of Urologic Nurses and Associates [36], this is not a standard practice. Appah et al. [41] surveyed inpatients with IUCs on medical and surgical units (n = 21) in an urban tertiary care hospital in Western Canada. The overall prevalence of catheter securement was 18% (8/44), and only 47% of medicine units and 92% of surgical units stocked securement devices.

Once the catheter is placed and secured, additional supplies and instructions are necessary for urine drainage and patient comfort, safety, and convenience. Additional supplies a patient may require include: leg drainage bag, overnight drainage bag, and a spare leg strap or device to secure the catheter tubing to the leg. Patients should be instructed on how to convert from a leg bag to an overnight bedside bag and vice versa, in order to minimize disruption of the closed catheter system. Leg bags generally hold 300–900 cc, whereas an overnight bag can hold up to 2000 cc. Drainage bags are discussed in Chap. 5.

As previously noted, IUCs should be removed as soon as medically appropriate. In the event that they are required for ongoing medical conditions, IUCs should be examined, changed and potentially removed every 4 to 6 weeks. This is generally done by clinicians or similarly qualified medical professionals. Immediately following placement, catheter

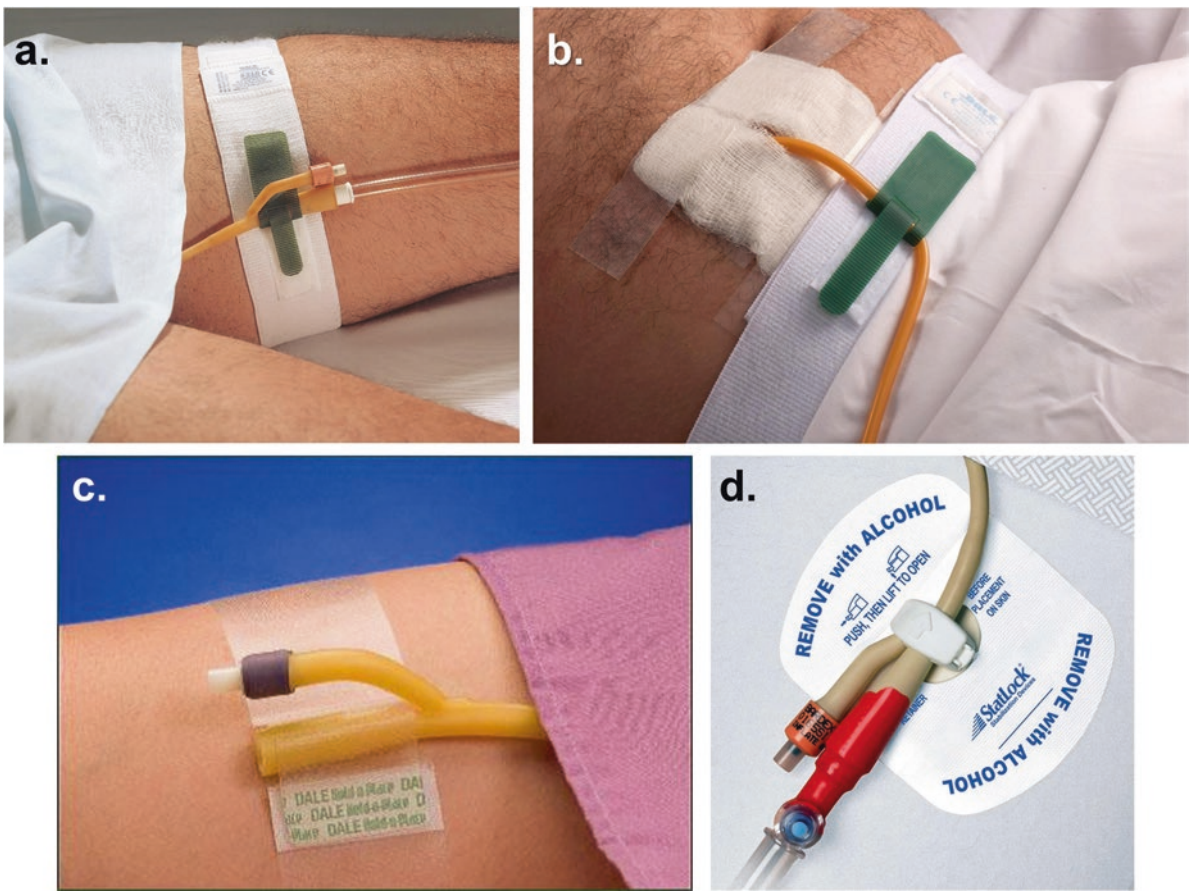


Fig. 1.27 (**a**) Urethral catheter secured on upper thigh with Velcro™ leg band (up to 20 in)—Courtesy of Dale Medical; (**b**) SP catheter secured with a Velcro™ abdominal strap (up to 56 in) —Courtesy of Dale Medical; (**c**) Urethral catheter secured on upper thigh with an adhesive patch—Courtesy of Dale Medical; (**d**) Urethral catheter secured with StatLock® adhesive anchor—Courtesy of C.R. Bard, Inc.

care instructions should be provided to the patient. This includes instructions on catheter maintenance (cleaning the urethral meatus and the exterior surface of the catheter itself), personal hygiene with the catheter (showering, etc.), cleaning and reuse of the drainage bags, sexual activity, how to recognize the signs and symptoms of UTI, and other potential catheter-related complications or problems.

Catheter-Related Complications

Catheter-related problems due to IUCs have existed as long as catheters have been utilized. Changes in catheter materials, design, and insertion techniques have reduced, but certainly not eliminated, such problems. From the historical development of "catheter fever," and despite the incorporation of the principles of sterilization, first described by Joseph Lister in the 1870s, catheter-related problems still exist today. IUC complications include: anaphylaxis, hypersensitivity (allergic reaction to latex), infectious complications such as symptomatic bacterial infection, cystitis, pyelonephritis, urosepsis, and epididymitis, catheter blockage (due to calculi, biofilms, and encrustations), catheter-related malignancy, hematuria, stones, urethral stricture and fistula from urethral injury, traumatic hypospadias, and periurethral urine leakage [16, 42]. Catheter complications can be related to various aspects of catheter design (e.g., material composition). Figure 1.28 depicts the morbidity rate of these complications. After symptomatic bacterial infection, the five most common IUC complications (with 45% morbidity) are caused by the mechanical interaction between the catheter and the urethra [16]. Severe mechanical trauma (e.g., partial damage, perforation and urinary leakage) occurs in as many as 90% of urinary catheterization procedures.

Wilde and colleagues [43] reported on 220 community-based long-term highly disabled IUC patients. Urethral catheters were used slightly more often (56%) than suprapubic (44%), for a mean of 6 years (SD 7 years). A high percentage of catheter problems were reported including 43% experiencing leakage (bypassing of urine), 31% having had a UTI, 24% with blockage of the catheter, 23% with catheter-associated pain, and 12% with accidental dislodgment of the catheter. The following is a review of some of these complications.

Increased Mortality and Morbidity

Catheters are detrimental to patients in many ways and cause significant morbidity and mortality when used incorrectly. Inappropriate IUC use has been equated to a "one-point restraint," because like a restraint, catheters can cause functional impairment, discomfort, and pressure injury [44]. Catheter-associated UTIs account for approximately 35–40% of all hospital-acquired infections in the US.

Although catheter-associated complications are mostly non-fatal, a high mortality rate (25–60%) has been reported

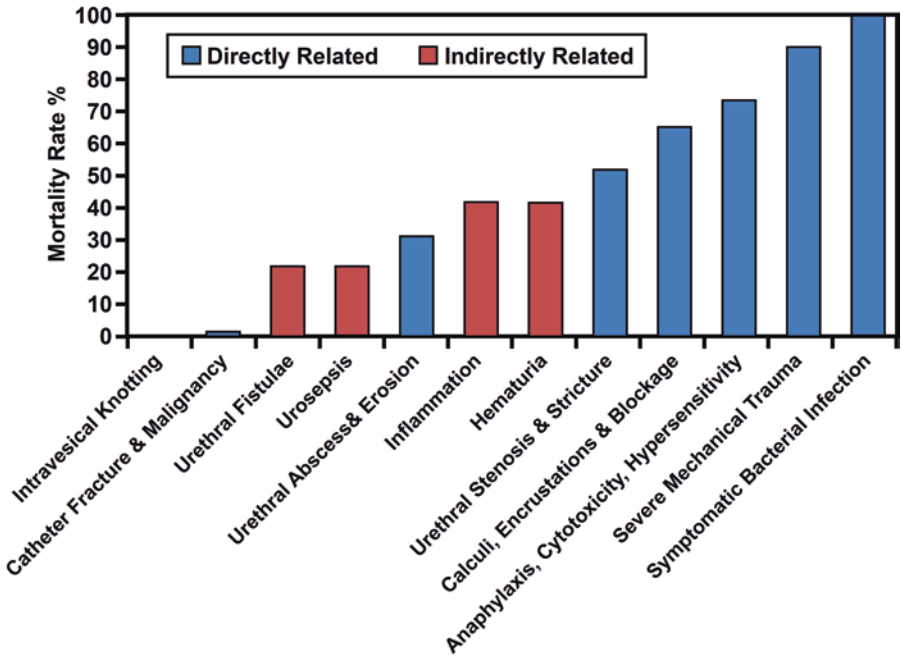


Fig. 1.28 Morbidity rate (%) of common complications arising from urinary catheterization procedures. Bars indicate complications which are directly related and indirectly related to mechanical interaction or trauma between the urethra and the urinary catheter, respectively [16]

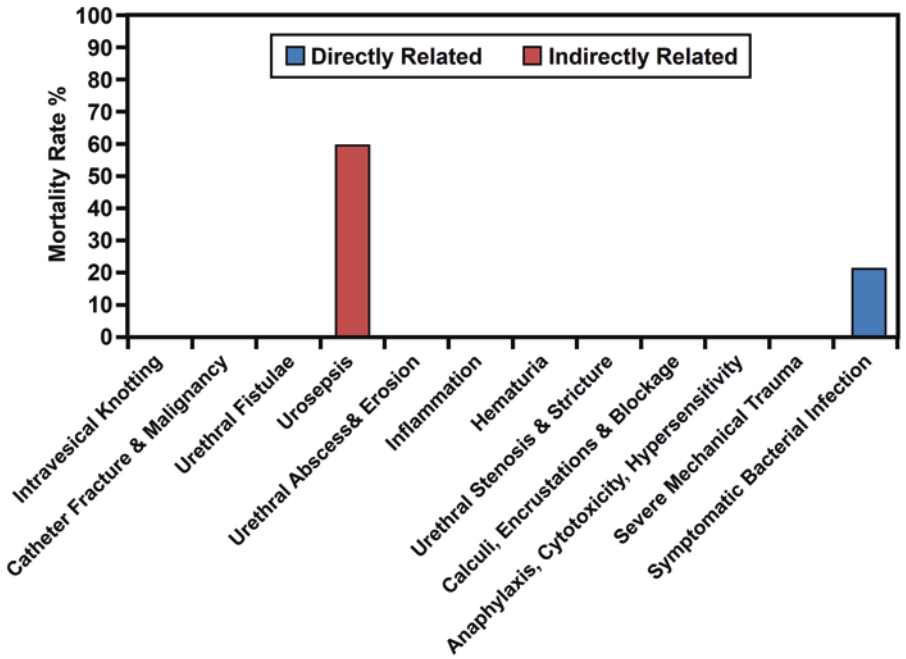


Fig. 1.29 Mortality rate (%) of major complications arising from urinary catheterization procedures [16]

for patients with UTIs who develop urosepsis. Whether this high mortality rate is due to inappropriate use of IUCs is unknown. According to Holyroyd-Leduc and colleagues [45], IUCs are associated with a greater risk of death—four times as great during hospitalization and two times as great within 90 days after hospital discharge. Nearly 13,000 deaths occur annually as a direct result of the complications associated with CAUTIs (see Fig. 1.29).

Infectious Complications

Bacteriuria

Bacteriuria is the most common complication from an IUC and develops within 30 days of the catheter being placed in >90% of patients. The most effective way to reduce bacteriuria is by limiting the number of patients that receive IUCs and by removing the catheter at the earliest appropriate time. Bacteria can colonize a patient's bladder through one of two routes: introduction into the urinary tract via the internal or intraluminal (34%) surface or external or extraluminal (66%) surface of urinary catheters [46, 47] (see Fig. 1.30). Intraluminal bacteria are transmitted through the entire length of the drainage tube and catheter. Intraluminal entry can occur from several causes: urinary stasis because of drainage failure, break in the closed system, from contamination of the urine collection bag or from urinary stasis in the bag with subsequent ascending infection. Extraluminally, bacteria contaminate earlier by being introduced and ascending into the urethra and bladder during catheter insertion or manipulation, which may indicate a lack of asepsis during initial insertion or occur by microorganisms ascending from the perineum along the surface of the catheter [48]. This latter route is presumed to be causative most often in women. In addition, fecal strains, primarily in female patients, contaminate the perineum and urethral meatus, are harbored in the labia and vaginal vestibule, and then ascend to the bladder along the external surface of the catheter to cause bacteriuria. Catheter biofilm formation (discussed later) and encrustation also contribute to entry of bacteria into the bladder along the biofilm that forms around the indwelling catheter.

It is critically important that clinicians and patients understand the difference between urinary colonization, bacteriuria, and infection. Colonization is almost ubiquitous with IUCs and does NOT warrant treatment of any kind. Colonization is a commensal relationship between "potential" pathogens in the bladder and urethra, and the host. In such patients, bacteria are found in the urine (i.e., bacteriuria), but there is no immune or inflammatory response from the host. Colonization is characterized by an asymptomatic patient, with a normal or near normal urinalysis, but a positive urine culture due to bacteria in the urine. Virtually all patients with a chronic IUC will be colonized with

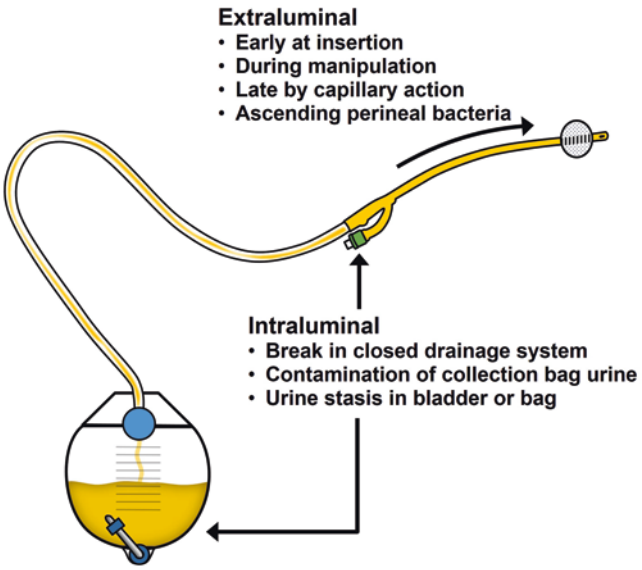


Fig. 1.30 Intraluminal and extraluminal pathways for bacteria invasion—Courtesy of Diane Newman

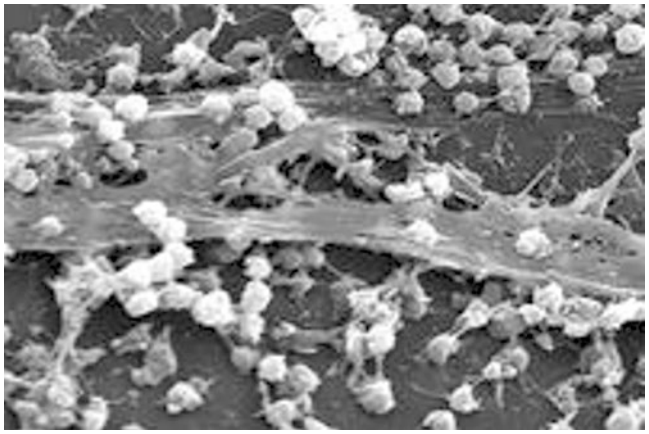


Fig. 1.31 Biofilm complex structure. Photograph from CDC Public Health Image Library: http://phil.cdc.gov/phil/details.asp

bacteria in the urine, and thus, will have a positive urine culture. Such individuals should not be treated with antibiotics unless indicated for reasons such as a symptomatic infection. Overtreatment or inappropriate treatment of such patients is a common cause of emerging bacterial antibiotic resistance.

Catheter Biofilms

Catheters are a good medium for bacterial growth, because once they gain access to the urinary tract, bacteria produce various adhesions, including hair-like fimbriae that allow them to firmly attach to the catheter wall [49]. Colonization of endogenous bacteria occurs from the urethral meatus, vagina, and rectum. Other causes of bacteria in urinary catheter drainage systems include exogenous sources such as those originating from contaminated health care personnel during catheter insertion or manipulation of the collecting system. These attached bacteria up-regulate their expression of certain genes, resulting in altered phenotypes that ultimately lead to the creation of biofilms [50]. Biofilms are complex structures that include bacteria, host cells, and cellular by-products (see Fig. 1.31). Biofilms replicate rapidly (see Fig. 1.32) and a mature biofilm can be formed in as little as 2 weeks after the setting of an IUC.

Biofilms is linked with infection because the biofilm provides a sustained reservoir for microorganisms that, after detachment, can infect the patient. Such complex environments also prevent effective antibiotic therapy [51]. These biofilms may cause further problems if the particular bacteria (e.g., *Proteus mirabilis*) produce the enzyme urease. With production of urease, the urine then becomes alkaline, causing the production of ammonium ions, followed by the crystallization of calcium and magnesium phosphate within the urine. These crystals are then incorporated into the biofilm resulting in encrustation, stone formation, and blockage of the catheter over a period of time [52]. The complex structures of the biofilm promote bacterial proliferation and protect bacteria from destruction from cleaners, antiseptics, antibiotics, and the host's immune system.

Biofilms containing microorganisms can develop intraluminally or extraluminally in urinary catheters. Intraluminal ascent of bacteria occurs within 48 h of IUC insertion faster than extraluminal ascension, which occurs within 72 to 168 hours (h). Biofilm formation within invasive medical devices is proposed as a primary mechanism in the development of certain diseases, antibiotic resistance and UTIs.

These bacteria within a biofilm are different from bacteria that float in urine (called planktonic bacteria). Bacteria within a biofilm exhibit a greater ability to communicate and exchange genetic information than do free-floating bacteria. This communication is hypothesized to promote antibiotic resistance and spread of the biofilm to other surfaces of the catheter and urinary epithelium.

The indwelling catheter provides the surface for biofilm formation. Biofilms can grow so thick, in some circumstances as to block a catheter lumen. Initially, IUC biofilms may be composed of single organisms, but can lead to multiorganism biofilms because the presence of the biofilm inhibits antimicrobial activity. Again, it is important to recognize that once biofilm is formed, the organisms within the biofilm cannot be eradicated by antimicrobial therapy or by irrigation [53].

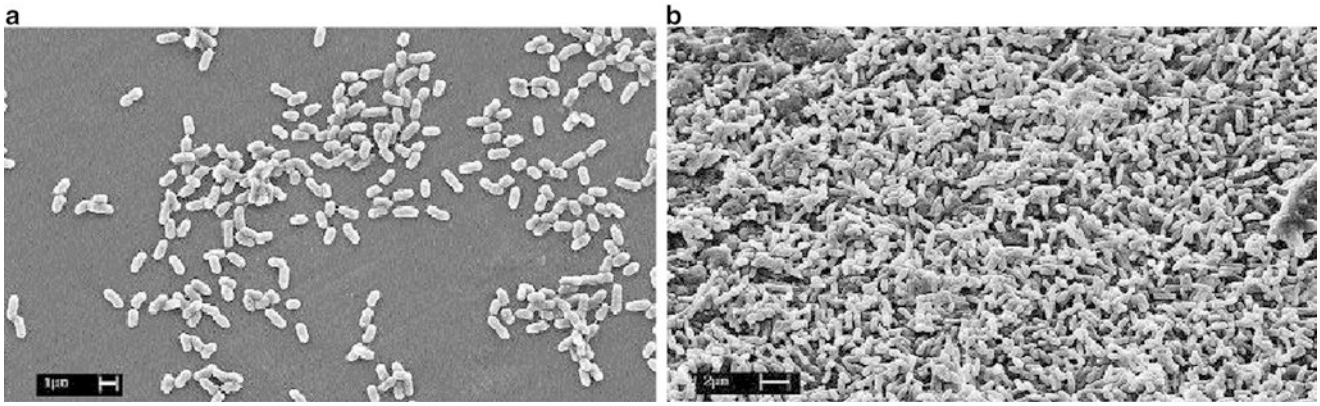


Fig. 1.32 (**a**) Biofilm replication 2 h primary adherence of bacteria on 100%-silicone catheter. (**b**) Bacterial biofilm (18 h later) on 100%-silicone catheter

Catheter-Associated Urinary Tract Infections (CAUTIs)

The bladder and urinary system are structured to prevent infection. The epithelial cells of the bladder lining are resistant to bacterial adherence and the flow of urine through the bladder helps to flush out bacteria. Despite this, the urinary tract is one of the most common sites of healthcare-associated infections (HAIs). Urinary tract infections that occur in patients with an IUC are referred to as catheter-associated urinary tract infections or CAUTIs. The Infectious Diseases Society of America [54] defines a CAUTI as the presence of 1000 (10^3) or more bacteria (colony forming units [CFU]) per milliliter of urine in conjunction with symptoms or signs of a UTI. The CDC National Healthcare Safety Network (a voluntary, secure, internet-based surveillance system managed by the Division of Healthcare Quality Promotion at the CDC) criteria for a CAUTI include any infection that occurred while the patient had an IUC in place for more than two calendar days on the day of the UTI, or the catheter was in place on the day of the UTI, or in place on the previous day, and then removed. The UTI criteria must be met on the day of catheter removal or the following day. The CDC definition does not include suprapubic catheters, only transurethrally inserted catheters. Symptoms can include, but are not limited to the new onset of bladder/suprapubic pain/pressure, bladder spasms, chills, nausea, or vomiting. Signs of an infection may include gross hematuria, cloudy urine, fever, and increased sediment or debris in the urine.

Catheter-associated urinary tract infections account for approximately one-third of all HAIs' in the US [55]. The risk of a person developing a CAUTI is directly related to the duration of catheterization. Every day that an IUC remains in place increases the patient's risk of a CAUTI by up to 7% per day. Beginning in 2008, the Center for Medicare and Medicaid began refusing to pay for services and treatment related to a HAI-CAUTI [8].

Several measures have been suggested to prevent HAI-CAUTI [8, 54]. One is the use of "bladder bundles" at the point of care. A bundle is a set of evidence-based practices which are designed to be implemented together to optimize treatment, prevent or reduce complications, and improve outcome [56]. The bundle for an IUC consists of educational interventions to improve catheter insertion management and use. Table 1.10 lays out the mnemonic "ABCDE" used for the bladder bundle described by Saint and colleagues [57] in their discussion on translating CAUTI prevention research into practice. A meta-analysis of the multiple studies that evaluated the impact of a bundle intervention strategy on CAUTI rates as a whole showed that bundle interventions can decrease CAUTIs [58]. Strategies included in the bundle were: (1) proper hand hygiene, (2) maintain the collection bag lower than the level of the bladder, (3) maintain unobstructed urine flow, (4) empty the collection bag at regular intervals and avoid allowing the draining spigot to touch the collection container, and (5) monitor CAUTIs using standardized criteria [8, 59]. Figure 1.33 is a pictorial of IUC nursing care practices that should be included in a bundle.

In a 2011 CDC sponsored survey of 183 hospitals, device-associated infections (ventilator-associated pneumonia, CAUTI, and central-catheter–associated bloodstream infection) accounted for 25.6% of all HAIs. A UTI ranked fourth highest of HAIs and of these, 67.7% were associated with a catheter [60]. According to a 2013 CDC report, there was a 6% increase in CAUTIs between 2009 and 2013, although initial data from 2014 seem to indicate that these infections have started to decrease (http://www.cdc.gov/HAI/surveillance/). Although the prevalence of IUC use in long-term care facilities is lower, the urinary tract accounts for up to

Table 1.10 The *ABCDE* bundle for prevention of CAUTIs

	Recommendation	Considerations
A	**A**dherence to general infection control principles (e.g., hand hygiene, surveillance and feedback, aseptic insertion, proper maintenance, education) is important	To ensure aseptic insertion, clinician should consider positioning of the patient to allow adequate visualization of the perineum, and correct position of the male penis to prevent urethral trauma during insertion (see Fig. 1.19)
B	**B**ladder ultrasound to measure bladder volume may avoid unnecessary catheter use	Development and implementation of an algorithm to guide hospital staff on steps to follow after catheter removal that will prevent unnecessary reinsertion, such as monitoring PVR urine volume
C	**C**ondom catheters or other alternatives to an IUC, such as intermittent catheterization or incontinence products should be considered in appropriate patients	External male catheters and pouches are an alternative for male patients who have UI. These external catheters will contain urine leakage and protect the skin from breakdown but do require assiduous attention to skin care under the collecting device to avoid ulceration of the glans penis
D	**D**o not use an indwelling urethral catheter unless medically appropriate	Follow the HICPAC guidelines for appropriate catheter insertion and removal
E	**E**arly removal of the catheter using a reminder or nurse-initiated removal protocol	Attention to catheter removal guidelines when such devices are no longer clinically indicated, to facilitate early and appropriate removal of IUCs

Adapted from [3, 57]

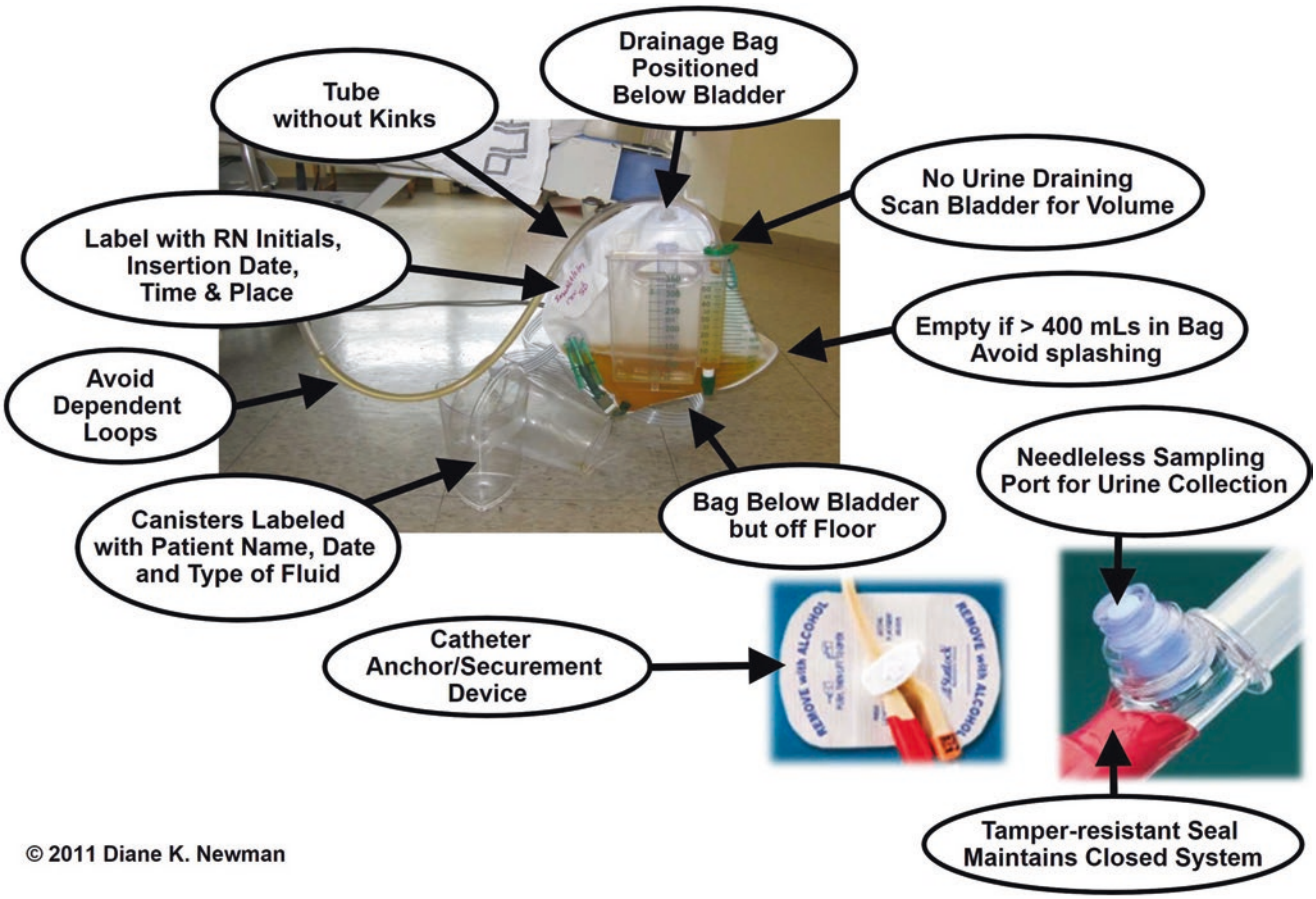


Fig. 1.33 IUC best practices

20% of infections in such facilities (http://www.cdc.gov/nhsn/PDFs/LTC/LTCF-UTI-protocol-current.pdf).

The most frequent pathogens associated with CAUTIs in acute care hospitals include: *Escherichia coli* (21%) and *Candida* spp. (21%), followed by *Enterococcus* spp. (15%), *Pseudomonas aeruginosa* (10%), *Klebsiella pneumoniae* (8%), and *Enterobacter* spp. (4%).

These are classified as complicated UTIs, because of the presence of a foreign body in the urinary tract predisposes the patient to a UTI and alters the body's ability to eradicate bacteria from the lower urinary tract.

If an infection develops, it is important to treat the infection as a complicated UTI because these patients can progress quickly to pyelonephritis, sepsis, and death. In such patients, it is important to exclude catheter drainage problems (kinking, clogging, etc.), as well as foreign bodies (stones, tumors, etc.) as a cause of infection.

Ideally, urine samples for culture should be obtained by removing the IUC and collecting a midstream specimen. If ongoing IUC is needed, ideally the catheter should be replaced prior to collecting a urine sample for culture, to avoid culturing bacteria present in the biofilm of the catheter, but not in the bladder. A microscopic urinalysis and urine culture should be obtained prior to initiation of antimicrobial therapy. A specimen can also be obtained by using a needleless sample port (see Fig. 1.34) that can be cleansed prior to specimen collection. Most standard catheter systems have such a port. Culture results from urine collected from the drainage bag of a newly inserted IUC should not be used to guide treatment.

If patients continue to develop recurrent (different organism) or relapsing (same organism) UTIs with an IUC, a full anatomic evaluation including cystoscopy and radiographic imaging is indicated. Prophylactic antibiotics are ineffective in preventing symptomatic infections in this setting and are discouraged as they promote antibiotic resistant microbial strains and fail to eliminate the bacteriuria [8]. As noted previously, biofilms are a potential cause of relapsing UTIs in this setting and can be very difficult to eradicate. These infections are frequently refractory to antibiotic therapy, unless the IUC is replaced [53]. Very little evidence exists regarding the use of measures to prevent UTIs in the setting of IUCs. Some authors have suggested the use of cranberry products and instillation of hyperchloride solution into the drainage bag has been suggested by some authors, but evidence to support such interventions are lacking. As mentioned previously, there have been no conclusive studies on the use of silver impregnated or antibiotic coated catheters for the prevention of UTI in chronically catheterized patients.

Fig. 1.34 Needleless port for urine specimen—Courtesy of CR Bard

Catheter Blockage Secondary to Encrustations from Biofilm Formations

Encrustations from biofilm formations is defined as the formation of crystalline deposits into the outer walls, lumen, and outlets of the catheter, which occurs in 50% of patients with IUCs [61, 62] (see Fig. 1.35). The encrustations on the outside surface of the catheter can break away into the bladder, forming a focus for bladder calculi and infections upon catheter removal. Prompt removal of the catheter and the encrustations are paramount in preventing further complications for the patient. Encrustation can also impair deflation of the balloon, therefore making it quite difficult to remove the catheter. The majority of patients who have recurrent catheter blockage (termed "blockers") usually exhibit symptoms of impending blockage. Several measures such as increased hydration, increased citrate or cranberry juice consumption, daily catheter irrigation, and acidic bladder instillations have been suggested, but these have only been shown to have efficacy in vitro. In general, there is a lack of well-controlled studies for prevention of encrustation in humans.

Encrustation is generally not problematic until it causes catheter blockage and prevents the drainage of urine. When blockage occurs, it results in infection, leakage around the catheter (bypassing), patient pain and inconvenience. A potential measure to reduce/prevent blockage includes decreased intervals between catheter changes. Catheter irrigations (bladder washouts) are not recommended although citrate has been used as a bladder irrigation fluid for dislodging blockages [63]. Patients who experience repeated blockages should have a cystoscopy, as the cause may be bladder calculi or related intravesical debris.

Fig. 1.35 Encrustations and crystalline deposits at catheter tip, blocking eyelets

Non-Infectious Complications

There are several non-infectious complications whose prevalence increases with IUCs in situ long-term. These include "bypassing", catheter dislodgement due to trauma or inadvertent balloon deflation, bladder stones, hematuria, mechanical trauma (e.g., urethral erosion causing traumatic hypospadias due to pressure necrosis) (see Figs. 1.13 and 1.14), false passage, squamous cell carcinoma of the bladder, pain, fistulas, and urethral trauma from removing a catheter with an inflated/incompletely deflated balloon.

Leakage Around the Catheter

Leakage around the catheter at the urethral meatus or SP site is also known as "catheter bypassing" Periurethral leakage, is a prevalent complication occurring in 25–65% of individuals with IUCs [29]. Wilde and colleagues [43] reported that 43% of patients with long-term catheters experienced leakage. Bypassing occurs when the bladder forces urine to exit adjacent to the IUC, because of one of a number of causes: irritation/inflammation resulting in bladder "spasms" or overactivity, catheter obstruction (from blood clots, stones, fecal impaction/constipation), improper catheter positioning, or drainage tube kinking. The etiology of bypassing is important to uncover in order to treat it effectively. Kinking of the catheter is an easily reversible cause that can be treated through improved nursing care and patient education. Other measures to prevent urine bypassing the catheter include ensuring no tension is placed on the catheter by adjusting the drainage tube length and securing the catheter to the upper thigh. Bladder spasms are an additional source of the leakage that can easily be treated includes bladder spasms. Such spasms may be due simply to the presence of the catheter, a foreign object in the bladder. Spasms can expel any residual urine sitting at the bladder neck, below the catheter eyelet (see Fig. 1.36). Spasms can be treated with an antispasmodic/antimuscarinic medication.

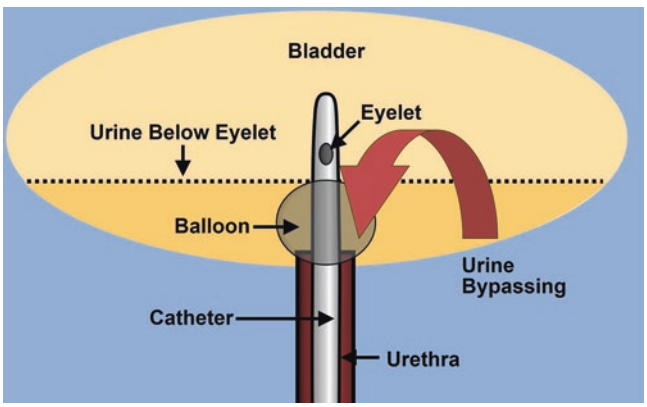


Fig. 1.36 Residual urine bypassing the catheter—Courtesy of Diane Newman

Catheter Expulsion or Inadvertent Dislodgment

Catheter expulsion or inadvertent dislodgment, defined as unintentional catheter removal, usually with the retention balloon inflated, can be a traumatic event. But the usual cause of a catheter expulsion is that the retention balloon has become deflated. However, other causative factors include acute delirium or chronic dementia, which compromises the patient's awareness of the rationale for catheterization and the consequences of removal. Detrusor overactivity or "bladder spasms," straining at stool, or excessive tension on the catheter can also lead to inadvertent removal. In addition, an IUC can be accidently removed by a nurse or caregiver, or accidently or deliberately removed by a confused or combative patient. Catheter dislodgement and inadvertent removal can be minimized by catheter securement and proper catheter education and counseling.

Urethra Complications

Urethra complications are usually mechanical in nature and occur more often in men with transurethral IUCs than with SP tubes [64, 65]. A hospital-based, prospective surveillance study by Leuck and colleagues [66] found that genitourinary trauma secondary to catheter use occurred in 1.5% of IUC days. The anatomy of the urethra makes it sensitive to minor injuries and urethral trauma can occur as a result of transurethral intervention. Urethral trauma is a more common problem in male patients with long-term catheters but it can also occur in females. Urethritis (inflammation of the urethral meatus) may occur due to frequent insertion of catheters, especially if there is a forceful catheterization against a closed sphincter [14]. Trauma to the urethra can occur during insertion and from "creep," (a failure of the balloon to completely collapse) as a small rim can make it difficult or impossible to remove the catheter (see Fig. 1.6). Urethral erosion or "tearing" is seen at the urinary meatus, occurs more frequently, and is more easily identified in the male patient, but can occur in both men and women [67]. Urethral erosion can lead to traumatic hypospadias due to pressure necrosis. Erosion can be minimized by catheter securement. Development of a urethral stricture may result from a urethral inflammatory response to repeated catheterization. Stricture is seen more often in patients using latex catheters, due to cellular toxicity from elutes in the latex rubber of the catheter. Difficulty with insertion may be a sign of the presence of a urethral stricture. Additionally, creation of a false passage can occur with traumatic catheter insertion, primarily in male patients with persisting urethral strictures. A false passage may also occur due to the voluntary or involuntary contraction of the external sphincter with catheter insertion resulting in a false passage at the membranous urethra (external sphincter), classically at the 6 o'clock position. Incomplete passage of the catheter through the length of the urethra may occur with the catheter

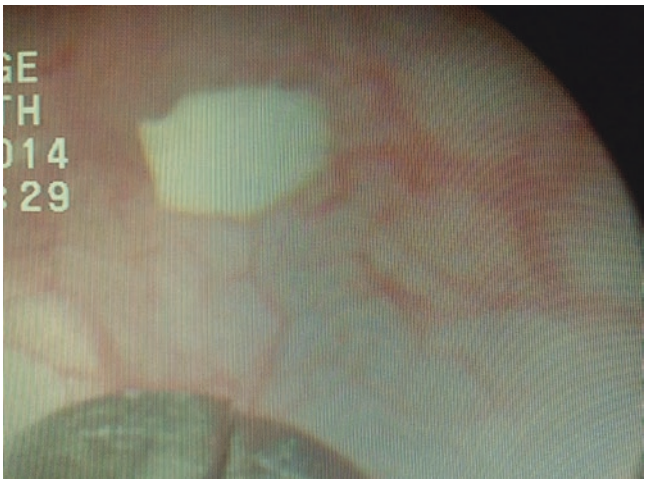


Fig. 1.37 Bladder stone

curling or kinking in the urethra. Curling or kinking can be manifested in pain, difficulty with catheter insertion, and lack of urine drainage upon placement of the catheter. When this occurs, the catheter should be completely withdrawn and reinserted [68].

Bladder Stones

Bladder stones may result from urease producing bacteria and related struvite calculi (see Fig. 1.37) which occur in both suprapubic and urethral IUCs. Katsumi et al. [65] conducted a retrospective review of records of men with a spinal cord injury who were managed with a urethral (n = 133) or SP catheter (n = 46). Incidence of recurrent bladder stones for the urethral catheter group was 38%, as compared to 41.3% in the SP group, but the difference was not statistically significant. This chart review also indicated no differences between the two groups as to incidence of renal calculi.

Squamous Cell Cancer

Squamous cell cancer accounts for less than 5% of bladder cancers and may be associated with IUCs [69, 70]. In spinal cord injury patients whose long-term bladder management is with an IUC, the estimated incidence of squamous cell cancer is 2–10% [71]. Screening for bladder cancer can be done via urine cytology, and periodic (e.g., yearly or biannual) cystoscopy. Hematuria is the most common presentation of squamous cell carcinoma and new onset unexplained hematuria may warrant a full evaluation in affected individuals.

Hematuria

Hematuria is commonly found in patients with IUCs. It can be symptomatic with pain and fever, or more commonly asymptomatic. Causes of hematuria include catheter trauma, UTI, malignancy, and stones. Careful consideration should be given to patients with recurrent hematuria. If a lower urinary tract cause is not found, then an evaluation of the upper urinary tract for a cause of the hematuria should be considered.

Catheter-Related Pain

Catheter-related pain is an important source of complaints from sensate patients with IUCs. Patients often report that IUCs are uncomfortable and painful [72]. Pain or discomfort is experienced initially during catheterization in individuals with intact periurethral sensation. Adequate lubrication and correct positioning of the urethra, as discussed previously, to accommodate normal curves can decrease pain in men during catheterization. Once in place, common causes of catheter-associated pain include bladder spasms, UTIs, catheter trauma, as well as meatitis in the male. Pain may also be experienced upon removal of the catheter and could be caused by trauma, encrustation on the external surfaces of the catheter and balloon, or incomplete deflation of the balloon, as well as "cuffing" or residual ridges from a deflated catheter balloon. In women, pain may be caused by hypoestrogenized urethral and perineal tissue. Transvaginal estrogen may be indicated in these women. Over time, pain and discomfort should lessen.

Skin Breakdown

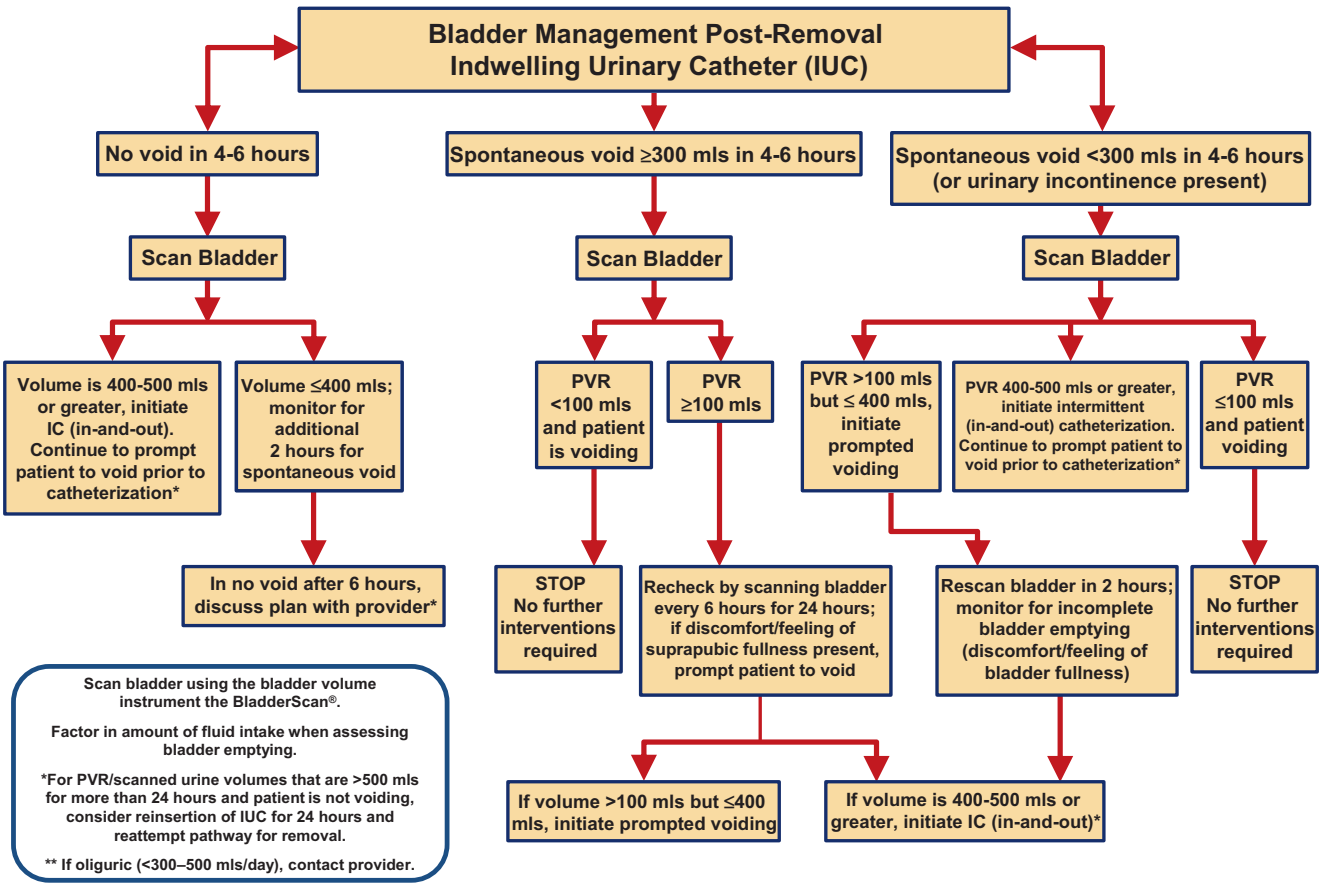
Skin breakdown related to a catheter has been reported [73]. Causes include catheter friction on the skin, wetness from urine bypassing, latex sensitivity, catheter tension, and from catheter straps.

Other rare complications of IUCs include bladder perforation, and vesicoenteric and vesicocutaneous fistula.

Prevention of Catheter-Related Complications

Preventive measures can be utilized and implemented to reduce IUC complications, particularly CAUTIs [74]. Preventative measures for encrustation, leakage per urethra, and leakage per SP tube site were discussed previously and will be discussed further. CAUTIs can result in increased hospital cost, patient length of stay, morbidity, and mortality. A CAUTI is costly, making the business case for prevention of these HAIs, a key component of a cost-control program [75]. Prevention of CAUTIs is therefore paramount.

First and foremost, appropriate placement, periodic re-evaluation (surveillance), and physical examination of the patient combined with timely removal of the IUC (when medically appropriate) are important measures to prevent complications. These measures are instrumental in meeting catheter-related guidelines in the acute care, rehabilitation, and long-term care settings. Unfortunate



IC= intermittent catheterization
PVR = post void residual, amount left in the bladder 10 to 20 minutes after voiding

Fig. 1.38 Bladder management pathway

but not uncommon reasons that IUCs are continued include provider's unawareness of the indications for catheter placement and therefore, reluctance to remove them, or further unawareness of whether the catheter is still warranted or necessary [12]. IUCs should be re-evaluated and replaced every 4–6 weeks. The interval depends on the providers' recommendation, as well as the risk of complications that may occur.

The majority of hospital systems do not have CAUTI prevention measures in place, although this is changing due to regulatory and financial pressures. Since CAUTIs in hospitals are no longer reimbursed in the US, this has spawned studies to determine measures to reduce CAUTI. Risk factors for CAUTI include: female gender, catheterization longer than 6 days, diabetes, malnutrition, ureteral stent, catheter placement outside of the operating room, active infection elsewhere, renal insufficiency, incorrect placement of drainage tubes and utilizing catheters for urine output measures [2]. Requiring documentation of the medical necessity for IUCs has decreased unnecessary catheter use. Hospitals have begun to implement catheter checklists with algorithms to decrease catheter use and enhance appropriate and timely removal of catheters as well as policies that promote prevention of complications (Fig. 1.38).

Nurses play a central role in catheter use since they are the main health care professionals who insert and cares for them. Current nursing practices are often based on a paradigm of outdated routines put forth from nurse to nurse. Care of these devices must shift from outdated practice to contemporary evidence-based care. Many IUC nursing care procedures currently employed are outdated practices for care of the catheter, drainage tube and bag, or practices not supported by research. In many cases, such practices have been shown to contribute to the development of complications (Fig. 1.33 Provides a pictorial review of evidence-based recommendations for IUC nursing care). A survey distributed to both nonfederal and federal US hospitals about prevention of hospital-acquired UTIs and other device-associated infections showed that nurses are not following specific practices to prevent CAUTIs [76]. In this study, only 9% of hospitals reported using an IUC stop order or reminder, only 14% used external (condom) catheters containment for men with

incontinence, and only about 30% used a portable bladder ultrasound scanner to determine PVR. In another study, 48% of RNs were unware that IUCs should not be routinely irrigated [77].

Currently, there is no set competency for RNs related to IUC insertion and care. An electronic survey at 75 acute care hospitals noted that only 47% of RNs reported competence in IUC insertion [78]. In undergraduate nurse education, nurses are taught about IUC insertion, complications, and management in a classroom and on a Sims model, but an actual insertion in a live patient often does not occur unless their clinical experience exposes them to a patient who needs to be catheterized. Some hospitals recognize this lack of competency and some have instituted a policy that every RN practice catheterization on a female and male Sims model during observation from a clinical nurse specialist.

Evidence-Based Indwelling Urinary Catheter Research

Clearly there are patients who benefit from or require IUCs, and the medical community should continue to strive to optimize care in such individuals. Evidence-based medicine is ideally utilized to create standard practices across various fields of medical practice to improve outcomes, reduce complications, and minimize costs. Such standards derive from the existing scientific literature. With respect to IUCs, there are few truly evidence-based practices, as the amount of literature is small.

Several Cochrane reviews have been completed on various aspects of IUCs and provide the following conclusions [15, 22, 63, 79–81]:

1. There is insufficient evidence to determine whether there is an optimal catheter type for those requiring either short-term [22] or long-term bladder drainage [82].
2. There is insufficient evidence supporting or refuting the concept of constant or intermittent catheter irrigation (referred to as "washouts") to prevent related complications [63]. However, IUC irrigation is not recommended in practice guidelines. The CDC guideline says "unless obstruction is anticipated (e.g., as might occur with bleeding after prostatic or bladder surgery) bladder irrigation is not recommended" [8]. Nevertheless, in a small (n = 43) community-based study, 60% of patients reported irrigating their catheters at some time during the prior 8 months, especially if the catheter was blocked or to prevent blockage [73].
3. For those requiring short-term catheterization, SP catheters have several advantages over urethral catheters with respect to improved patient comfort, decreased risk of bacteriuria, and re-catheterization. However, there is not enough data to comment on the risks associated with placement of SP tubes [15, 80].
4. Intermittent catheterization is associated with lower rates of bacteriuria than IUCs in those requiring short-term catheterization [15].
5. Prescribing prophylactic antibiotics is not recommended in the patient with a long-term IUC. There is limited evidence that receiving prophylactic antibiotics reduced the rate of bacteriuria and other signs of infection, such as pyuria, febrile morbidity, and gram-negative isolates in patients' urine, in surgical patients who underwent bladder drainage short-term (e.g., for at least 24 h postoperatively) [79]. There is limited evidence that prophylactic antibiotics reduced bacteriuria in non-surgical patients.

There are several other areas in need of high quality evidence-based research:

1. *Noninvasive bladder monitoring prior to placement and following removal of IUCs*

All current guidelines on prevention of CAUTIs recommend the use of bedside portable bladder scanners as a noninvasive method in detecting PVR urine and preventing unnecessary catheterizations [83–87]. Scanning the bladder to determine urine volume is especially important post-IUC removal and is part of a bladder management program (Fig. 1.38). Palese et al. [88] noted that the systematic use of the portable bladder scanner in the peri-operative period could increase the appropriateness of catheterization and reduce patient discomfort, costs and days of hospitalization associated with UTI caused by catheterization. Standard of practice in most acute and rehabilitation centers is to scan the bladder to determine need for catheterization. However, it is important to recognize that there are limitations to using the bladder scanner, including the need for proper training. Furthermore, such diagnostic equipment is especially inaccurate in the setting of obesity, lower abdomen scars, or ascites [89]

2. *Clamping the catheter prior to removal*

An IUC provides constant and free drainage of urine, which keeps the detrusor muscle in a state of continual collapse or relaxation. Whether this has clinical implications for bladder elasticity and contractility once the catheter is removed is unknown. It has been promulgated for years that clamping and unclamping an IUC (sometimes referred to as "bladder reconditioning" or "bladder cycling") prior to removal allows the bladder muscle to regain tonus by applying stretch intermittently. In such situations, clamping has been suggested to stimulate normal bladder filling and

emptying. It is theorized that such maneuvers promote optimal bladder function at the time of catheter removal [90]. Clamping the IUC before its removal is reported to decrease the frequency of urinary retention and shorten the time to return to normal bladder function. However, the evidence is equivocal [91] which may be due to the diversity of clamping protocols being compared in clinical trials. A Nyman et al. [92] randomized trial of patients with hip fractures did not show any advantage or disadvantage to IUC clamping prior to removal. These authors felt that since it was an additional task for the nursing staff, it was not indicated. Moon et al. [93] also found that bladder reconditioning through IUC clamping had no noticeable benefits in a small sample size (n = 60) of stroke patients and may induce additional problems (discomfort, infection). A 2007 Cochrane review found that evidence on the strategy of IUC clamping before removal of a short-term IUC was inconclusive [94].

3. *Use of catheter valves*

In many centers, patients do not attach a drainage bag to an IUC for continuous drainage, but rather insert a catheter valve (CV) or simply a catheter plug (see Fig. 1.39a, b) in the drainage lumen, allowing urine to be stored in the bladder and intermittently emptied. The bladder is drained periodically by releasing the valve or removing the plug at regular intervals, such as every 2–4 h [95] (see Fig. 1.39c). Most CVs are tap-like devices that fit into the end of the catheter (urethral or suprapubic) [96]. Catheter valves offer an alternative to using a urinary drainage bag. In patients who have an IUC over a long period of time, a CV may provide considerable convenience for the patient in that they do not need to maintain a catheter bag and related tubing. Whether such CVs or plugs have any effect on bladder function, capacity, and tone in the long-term is unknown.

The benefit of CVs has been mostly theoretical. For example, continuously draining catheters can mechanically traumatize the bladder mucosa as the balloon rubs against the collapsed bladder wall. A CV may reduce this risk by allowing the bladder to fill, thus lifting the bladder wall away from the catheter. A CV may also decrease tension on the bladder neck from a hanging, partially filled drainage bag. Sabbuba and colleagues [97] reported on a laboratory experiment using automatic and manual valves. Their findings showed that CVs regulated intermittent flow of urine through catheters, thus increasing the time until the formation of crystalline biofilm on the catheter. The most beneficial effect was recorded when urine was released from the bladder at 4-h intervals throughout the day and night by an automatic valve. Some data suggest that these valves reduce CAUTIs and may be preferred by some patients. A mini-review by Van den Eijkel and Griffiths [95] reported on two CV studies [98, 99] which found no statistically significant difference in the incidence of bladder spasms or pain between the CV and standard continuous bladder drainage, however there was a statistically significant patient preference and satisfaction in favor of the CV. Recent research on the CV shown in Fig. 1.39c demonstrated that this CV is a patient-friendly alternative to a drainage bag [100].

Catheter valves are not appropriate for patients with uncontrolled detrusor overactivity (spasms), poor bladder capacity, or upper tract deterioration due to ureteric reflux. Such patients will be unable to store adequate volumes of urine in the bladder under low pressure with the resultant potential for upper urinary tract (kidney) deterioration. Those with baseline renal impairment should only use such devices with careful and ongoing monitoring of renal function. Patients or their caregivers must have the hand dexterity to manipulate the valve mechanism and the mental ability to empty the bladder regularly to avoid complications such as infection, bypassing, and upper urinary tract injury. Additional research is needed on the optimal CV device, choosing the appropriate candidate for this intervention, minimizing risks associated with CVs and the optimal interval for emptying.

4. *Catheter-associated bacteriuria and infection*

There is a deficiency in the knowledge and quality of studies about the clinical significance of catheter-associated asymptomatic bacteriuria (CA-ASB) and CAUTI. Firstly, terminology is not standardized between the two. Secondly, further investigation is needed to understand the relationship between CA-ASB and CAUTIs. For example, it is important to determine whether a reduction in CA-ASB results in a decrease in CAUTI [54].

Developments in materials that prevent biofilm formation may help in the prevention of catheter-associated bacteriuria and thus prevent CAUTI [17]. Despite the considerable research that has gone into developing biocompatible materials, biofilm formation leading to encrustation and potentially subsequent infection is still problematic. Additional research into treatments that may breakdown biofilms may also be valuable.

Additional areas of potential investigation include optimizing the materials in the manufacture of IUCs to minimize urethral erosion, stone formation, risk of malignancy, and infection. Such materials should be non-immunogenic, non-allergenic, and anti-microbial. Furthermore, such an optimal catheter would allow long-term indwelling time, with minimal patient discomfort and ease of exchange at a low cost.

5. *Frequency of catheter change or what is the duration of an individual "catheter life"*

When to change a catheter has been a subject of debate for clinicians, patients and insurers for many years. In practice, long-term IUC changes are routinely done every 30 days or monthly and usually by a home care nurse or less frequently by urology practices [101]. This schedule is likely much more related to payment structure (e.g., Medicare will cover

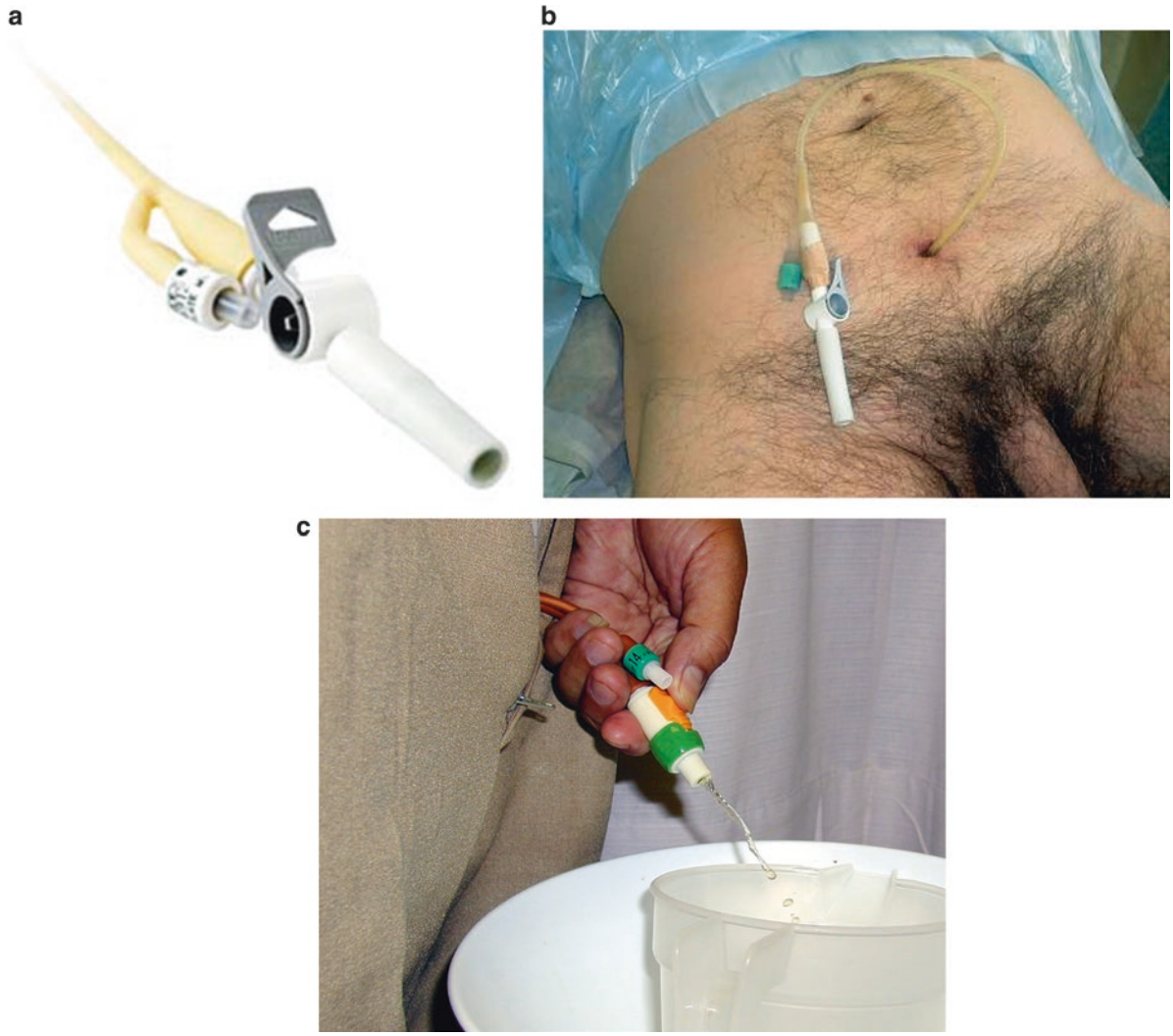


Fig. 1.39 (**a**) Flip-Flo catheter valve with catheter attached—Courtesy of C.R. Bard, Inc. (**b**) Flip-Flo catheter valve attached to a SP tube. (**c**) Patient opening a catheter valve to drain urine

a monthly home care visit to change an IUC) than to patient need or evidence-based medical practice. Although not common, there are reports of IUCs having an extended catheter life as long as 6 weeks to up to 3 months. However, unscheduled catheter changes occur at very high rates, more often than routine changes [54]. Current guidelines do not recommend routine, scheduled fixed-interval catheter changes, instead, IUC changes should be based on clinical indications (e.g., infection, obstruction) or when the closed system is compromised [8, 54]. However, even this recommendation is based primarily on clinical opinion rather than evidence-based research.

Raz et al. [102] performed a prospective randomized open clinical trial at two long-term care facilities to determine whether a catheter should be changed at the time of initiation of antimicrobial therapy in symptomatic patients with IUCs. Patients ($n = 27$) were randomized to IUC replacement or no replacement before initiating antimicrobial therapy in the setting of a symptomatic UTI. In this study, a urine specimen was obtained for culture either from the existing IUC or the newly reinserted catheter. Outcomes indicated that clinical and bacteriological outcomes were improved when long-term IUCs were replaced before initiating antimicrobial therapy for symptomatic UTI. However, this finding has not been widely utilized in clinical practice. The International Consultation on Incontinence [2] recommends pre-emptive routine IUC changes in patients who experience recurrent obstruction and blockage. This group also recommends monitoring the patient to identify a pattern of what they term "catheter life" and schedule pre-emptive changes prior to the

onset of catheter-related problems. However, it is clear that in long-term IUC patients, the optimal timing or clinical indications for catheter changes are not well understood and further research should be directed towards resolving this important issue.

6. *Patient reported outcomes/quality of life*

Quality of life is an important consideration for those with IUCs, especially given the variety of catheter options (i.e., suprapubic vs. urethral) and types. Further research is urgently needed from the patient's perspective. Cotterill and colleagues [103] validated a 16-item catheter-related quality of life (C-IQoL) instrument (ICIQ-Long Term Catheter quality of life [ICIQ-LTCqol]) that consists of two scored domains: catheter function and concern (nine items) and lifestyle impact (three items) and four stand-alone items, relating to pads, pain, sexual activity, and bladder spasm. If used in clinical research, this instrument could add to the scant research base in this area.

Best Practices for Management

Nevertheless, even without a strong evidence base, certain principles remain applicable to IUCs, on which most or all clinicians would agree. First among these is the use of sterile technique on insertion of an IUC. Sir Joseph Lister was the forerunner of the idea of sterile technique, which he based on Louis Pasteur's principles of microbiology. Other important best practices that have been recommended by urology, expert nurses, organizations, and professional and government guideline are summarized in Table 1.11.

Management of Long-Term IUCs

Little evidence exists to guide clinicians in long-term management of IUCs or guide patient and caregivers in self-management [2]. Patient education is lacking in those patients who have IUCs in place for short- or long-term periods. Safdar and colleagues [125] reported on the perspectives of a small group (n = 20) of hospitalized patients who had IUCs. A majority (75%) of patients reported inadequate education on the consequences of IUCs and all reported receiving no information on alternative methods of excretion. Patient engagement and awareness of IUC uses, risks, and alternatives have implications in reducing the risk of CAUTIs. Also, explaining to the patient the reason for the IUC, as well as its purpose can assist the patient in self-management.

Roe and Brocklehurst [126] used semi-structured questionnaires to collect information from 36 patients who had an IUC. They concluded that if patients understood more about their catheter and its function, they would better accept and manage the catheter. Thus, initial education on normal bladder physiology, the purpose of a urinary catheter, how to care for the catheter, and problems that might arise should be provided to all patients who receive an IUC, and should involve family members and caregivers who may be involved in catheter management.

Few studies have explored subjective perceptions of people living with a long-term IUC, let alone their preferences for different types of IUCs, or how such decisions are made. Persons living with a long-term IUC view the catheter as "part of me," an integral part of their lives, rather than a foreign object [127, 128]. But there remains a stigma associated with its visibility, especially if someone draws attention to it, or if there is a urine-related accident. In such instances, the catheter can cause feelings of alienation, embarrassment, and shame.

The clinician prescribing or inserting the catheter plays a vital role in educating the patient about the device. They need to recognize that catheter adjustment takes time and it is the clinician's responsibility to guide the patient and/or family to acceptance. The clinician will need to identify a reliable and ethical medical supplier of catheter equipment. In addition, the clinician should discuss the need to assess for patterns of catheter-related problems, as this could direct future interval catheter changes. If the patient is sexually active, the patient should be instructed about intimacy with an IUC that includes modifications for comfort during sexual activity.

Some experts recommend that patients self-monitor using a diary to record observations and measurements of fluid intake and output, urine characteristics, and sensations of flow, so as to identify possible problems at the earliest stage as possible [129]. Teaching the patient to monitor urine flow as part of self-management is simple and may be beneficial in preventing UTIs and treating them early. This would include noticing the color of the urine and increasing fluid intake.

Patients should be educated on the two different types of drainage bags, the leg bag and overnight bag. The overnight bag can be worn at all times, but the leg bag should only be worn during the day (see Chap. 5). Patients should also be instructed on catheter management during personal hygiene activities such as showering or bathing.

Throughout the day, the patient should ensure that the catheter is draining and that the drainage bag does not overflow. Hygiene is important in preventing infection. Daily personal hygiene around the catheter site is recommended. The urethral meatus or the area surrounding the SP tube site should be cleansed with soap and water on a daily basis. Providing educational tools on care and use of the urinary catheter drainage bag can help answer basic questions.

Table 1.11 Summary of best practices for management of indwelling urinary catheters

Practice recommendations	Rationale
Catheter selection and preparation	
• Ensure that only trained personnel insert urinary catheters, especially suprapubic catheter insertion	• Minimizes associated trauma, pain, discomfort and catheter-associated infections [8, 26]
• Choosing the type and size of an IUC should be individualized	• Many clinical variables dictate the choice of catheter including: allergy or sensitivity to catheter materials, history of symptomatic UTI, patient preference and comfort, previous catheter history, and reason for catheterization
• Size 14–16 Fr recommended	• Larger size diameter catheters (e.g., 22 Fr–24 Fr) can obstruct periurethral glands leading to CAUTI rates, resulting in greater leakage, and are more likely to obstruct normal periurethral secretions. Smaller catheters, in an adult patient, are more likely to provide suboptimal drainage due to small lumen size
• Use a 10 cc balloon size for most catheterizations	• A larger balloon (30 cc) will potentially increase the amount of undrained urine that pools below the level of the catheter lumen thus increasing the risk of infection. Larger balloons are indicated only under certain circumstances (i.e., postoperative hemostasis for certain prostate surgeries)
• Select a preconnected catheter insertion kit with a metered drainage bag if the patient requires accurate urinary output monitoring	• If measurement of urine output becomes necessary, a metered drainage bag assists with hourly monitoring of urine output.
• Consider IUC systems with pre-connected, sealed catheter-tubing junctions (called closed systems) and avoid disconnecting the catheter from the drainage bag	• Unnecessary disconnecting of the catheter from the drainage tube increases the chance of introducing bacteria into the catheter [104, 105] • Closed drainage has been shown to significantly reduce the rate of a CAUTI [52]
Catheter insertion	
• Always insert a catheter using aseptic technique and sterile equipment. If the catheter touches any part of the body other than the urethral meatus, it must be discarded	• Bacteria can be introduced with the catheter at insertion as a result of poor aseptic technique. Because the bladder is sterile, it is important that bacteria from the genital tract not be introduced into the bladder via the urinary catheter
• Proper hand hygiene should be maintained immediately before and after insertion or any manipulation of the catheter and system • Wear gloves whenever handling the catheter system	• Bacteria can be introduced with the catheter at insertion, as a result of poor aseptic technique
• Consider two person catheter insertion when appropriate	• Second person can assist if improved meatal visualization is needed and can verify aseptic insertion
• Female patients should be positioned so clear visualization of the perineum and urethral meatus is maintained • The male penis should be held in a near vertical position during insertion	• Proper positioning maintains optimal conditions for sterile catheter insertion and can minimize trauma
• Perform perineal assessment prior to catheter insertion	• Perineal inspection is important to prevent long-term complications of IUCs such as skin breakdown and traumatic urethral erosion
• Do not pretest the balloon	• Pretesting of the balloon may create cuffing and discomfort with insertion
• Disinfect and cleanse urethral meatus using antiseptic solution prior to catheter insertion	• Reduces or eliminates peri-meatal bacteria
• Coat the catheter prior to insertion using generous amounts of sterile lubricant	• Minimizes urethral trauma and maximizes patient comfort during insertion
• Use an antiseptic as a lubricant in select catheterizations	• The routine use of 2% lidocaine urethral instillation prior to catheter insertion is not recommended. Toxicity has been reported in patients with a disrupted mucosal barrier who have received Lidocaine gel. To be beneficial, the lubricant should be indwelling in the urethra for at least 15 minutes
• Use one catheter for one insertion attempt • If the catheter becomes contaminated during insertion, obtain a new catheter insertion kit	• Maintain sterility of the catheter during insertion

(continued)

Table 1.11 (continued)

Practice recommendations	Rationale
• If a large volume of urine (e.g., >800 mLs) is found when catheterizing, drain entire amount	• Practice of clamping a catheter, to intermittently or incrementally drain a distended bladder (>500 mL), is not recommended. There is no evidence that rapid complete emptying of urinary retention results in complications
Catheter Securement	
• Secure the catheter by using a catheter-stabilizing device (referred to as an anchor strap or securement device)	• To prevent tension on the posterior urethra, to prevent urethral movement, and to prevent urethral trauma and meatal tear • Maintains catheter in a manner that prevents accidental disconnection • Promotes urine drainage • Maintains catheters below the level of the bladder to prevent accidental backflow of urine • Ensures that the catheter is not accidentally disconnected
• Always apply a securement device to a dry, clean area without lesions or redness	• For an adhesive device to adhere, the skin must be clean and dry
• Catheter securement device should be in place for duration of catheter use	• Securement is especially important in men as the catheter and penis should be secured in an upright position to prevent ulceration from occurring at the curve in the urethra and to prevent formation of hypospadias, erosion, etc. at the urethral meatus
Catheter maintenance	
• Maintain a closed, sterile drainage system. Replace the catheter and collection system using aseptic technique if breaks occur in aseptic technique, catheter becomes disconnected from the drainage tubing or leakage occurs	• Disconnecting the catheter from the bag should be minimized in order to best maintain the closed catheter system and lessen the risk of infection
Meatal and catheter cleaning	
• For routine catheter maintenance once the catheter is placed, cleanse the urethral meatus using soap and water or a perineal or incontinence cleanser; do not apply antiseptic solutions, ointments, or creams when cleansing the meatus • The urethral meatus or the area surrounding SP tube site should be cleansed with soap and water or with routine daily hygiene (e.g., when bathing or showering) • Cleaning of the catheter should be pursued if soiling of the catheter and meatus occurs with fecal material	• Daily hygiene is important in preventing ascending infection. Use of plain wipes (disposable wipes that contain purified water, aloe and vitamin E) among adult catheterized patients has been shown to decrease CAUTIs. There is insufficient evidence to recommend twice-daily meatal cleansing with soap and water or a povidone-iodine solution [8]
• Gently wash around the urethral meatus at the catheter entry site and the catheter, using a clean washcloth or wipe • Cleanse catheter along its length from the meatus towards the catheter to the hub (see Fig. 1.40)	• Aggressive cleaning may be associated with increased complications
• Avoid use of antiseptics at the urethral meatus	• Meatal disinfectants or antibacterial urethral lubricants do not prevent infection and may lead to resistant bacteria at the meatus [8]
Urine drainage	
• Periodically inspect and ensure that the catheter is draining, that the drainage bag does not overflow and avoid dependent loops	• Catheter obstruction may lead to pain, infection, and other complications
• Maintain unobstructed urine flow by keeping the drainage tube straight and close to the end or foot of the bed such that urine drains directly into the bag • Placing the drainage bag below the level of the bladder at all times (e.g., during travel, surgery, when transferring). Secure the tubing to the bottom sheet using the clip on the drainage tube bed as possible.	• A dependent loop is a configuration of catheter tubing where the drainage tube dips below the entry point into the catheter bag [106] • Ensures an unobstructed urine flow and prevents urine stasis • A drainage tube that sags below the level of the collection bag can increase the risk for a CAUTI [107]

Drainage Bags	
• Drainage bags should be emptied on a routine basis (e.g., at least every 4–6 h) or when urine in the drainage bag reaches 400 mLs	• Drainage bag represents a large reservoir of pathogens and stasis of urine promotes proliferation of bacteria • Routine bladder emptying will avoid ascending migration of bacteria into the catheter system • Weight of a large volume of urine in a full drainage bag increases tension on the drainage tube and catheter, potentially increasing risk of urethral trauma
• Avoid contact of the drainage spigot with the non-sterile collecting container • Avoid splashing, and prevent contact of the catheter drainage port with container	• Drainage bags have integrated antireflux valves to prevent bacteria migration • As most insurers only cover two bags per month, drainage bags on long-term IUCs should be cleaned and reused • Cleaning methods include the use of dilute beach or vinegar solutions
• Use a separate, clean collecting container for each patient and replace the container every 24 h • Date and label container with patient initials • Keep drainage devices on opposite sides of the bed and keep drainage devices in semi-private rooms on opposite sides of the room	• Replacing the container daily will minimize contamination • Separate containers avoid cross-contamination of bacteria from one patient to another
Management of obstruction	
• Catheter irrigation is not recommended unless obstructed by blood clots or other debris	• Routine catheter irrigation has not been shown to reduce complications
• If obstruction is anticipated (e.g., post-surgery blood clots), closed continuous bladder irrigation can be used to prevent obstruction from clots and surgical debris	• Continuous bladder irrigation is useful in preventing blood clots from forming and in clearing existing clots
• If a catheter in a patient with a long-term IUC develops multiple episodes of blockage, consider changing catheter more frequently (prior to time blockage occurs) or switch to another catheter material	• Silicone might be preferable to other catheter materials to reduce the risk of encrustation in long-term catheterized patients who have frequent obstruction [8]
• If obstruction is suspected, use a bladder scanner to determine urine volume in bladder	• Bladder scanning is a noninvasive technique to assess bladder volume
Catheter changing and reinsertion	
• Changing IUC or drainage bags at routine, fixed intervals is not recommended • If patient has multiple problems with catheter use, leakage, obstruction and infections, consider changing catheter more frequently	• Research is not available to support or refute routine changes of chronic IUCs [101]
• Do not clamp the catheter or drainage tube	• There are few, if any indications for purposefully obstructing drainage from an IUC. Such practices may result in patient discomfort and infection
Removal	
• Remove IUCs in the late evening (e.g., 10 PM) in anticipation of morning micturition	• IUC removal in the evening has shown a significant increase in the time to the first void after removal and consequently a greater initial voided volume, resulting in a faster return to a regular voiding pattern [108] • Added advantage may be earlier discharge in hospitalized patients
• Following IUC removal, implement a bladder management protocol that includes a trial of voiding	• An algorithmic approach to bladder management following catheter removal should be followed (see Fig. 1.38) and a "Trial of Voiding" initiated (see Table 1.12)
• Provide portable bladder volume ultrasound devices (e.g., BladderScan®) on nursing units to assess adequate bladder emptying • Bladder monitoring should not be performed with repeat catheterizations when a bladder scanner is available and appropriate for noninvasive bladder assessment	• Use of a noninvasive technology (e.g., bladder scan) is preferred as compared to catheterization in assessing bladder emptying to minimize urethral trauma and infection [58]

(continued)

Table 1.11 (continued)

Practice recommendations	Rationale
• Based on assessment of bladder function (e.g., incomplete bladder emptying/urinary retention, urinary incontinence), investigate alternatives to an IUC (e.g., intermittent catheterization, external catheters or pouches, toileting assistive devices, incontinence absorbent products)	• Consider using external catheters as an alternative to an IUC in cooperative male patients without urinary retention or bladder outlet obstruction [8] • Consider alternatives to chronic IUCs, such as intermittent catheterization, in spinal cord injury patients, in children with myelomeningocele and neurogenic bladder to reduce the risk of urinary tract deterioration [8] • Ensure that nurses have adequate time, training, and equipment to implement alternative measures (e.g., intermittent catheterization, external catheters) with the required frequency [113]
Obtaining a urine specimen and treatment of UTI	
• Obtain urine samples aseptically through a needleless port. Scrub the needleless port with alcohol for 15 seconds, allow to dry and aspirate the urine with a sterile syringe	• This method avoids breaking the closed catheter system and minimizes risk of infection
• Consider changing the catheter before obtaining a specimen for culture, since cultures obtained through the existing infected catheter may be inaccurate	• Because of the presence of biofilms, a urine specimen from the contaminated catheter system may be inaccurate in identifying the causative bacteria residing in the bladder
• Urine specimen should be cultured within 2 h of its collection	• Overgrowth of bacteria can readily occur with mishandled specimens, which will cause a false positive or unreliable culture result
• Change the entire catheter and drainage system once the diagnosis of CAUTI has been made and prior to initiation of antimicrobials	• Not changing the catheter system prior to implementing treatment makes eradicating bacteriuria or candiduria difficult and can lead to the development of antimicrobial resistance. Removal of the "bioburden" of the catheter-associated biofilm helps to decrease the severity of inflammation and the probability of recurrence [102]. • May not be realistic to expect healthcare personnel to remove, change a urinary catheter, or both prior to collecting all urine cultures [50]
Performance measures	
• Implement educational strategies, catheter avoidance, policies for catheter insertion, catheter selection, daily necessity review and limit catheter days	• These are preventative measures which have shown success in decreasing CAUTI rates [114, 115]
• Optimize staff compliance with periodic educational programs	• Identify and educate staff who can then serve as quality improvement experts for CAUTI prevention • The surge in CAUTI incidence due to the increased use of catheters over an extended time period has prompted the development of infection control protocols and initiatives in health care settings [116]
• Maintain an annual competency evaluation for RNs relating to IUC placement and maintenance	• One of the first steps in implementing evidence-based practices is to focus on competencies and feedback on performance. Six percent of all inpatient urologic consultations was shown to be related to complications from catheter placement, most of which were inserted by trainees [117] • Registered nurses play a central role in safe IUC practices because they are the primary clinicians who insert them and care for patients with them. Competencies related to IUC insertion should be maintained and validated at regular intervals [78] • Skill interventions aimed at clinicians may be important to reduce non-infectious complications [64]
• Implement a facility-wide surveillance program that includes the use of checklists and/or electronic monitoring	• Has been shown to reduce IUC utilization rates and ultimately CAUTIs, results in a culture change for the facility, and enhances teamwork and ownership among the disciplines involved in the process [10, 118]
• Identify personnel who have proper catheter insertion and maintenance training • Assure compliance with documentation of catheter insertion and removal dates • Conduct random audits of selected units and calculate compliance rate. • Conduct daily evaluation of continuing indications for the use of an IUC	• Critical need for hospitals to have proper equipment and resources (such as mechanical lifts and lift teams) for turning of obese or edematous patients to protect the safety of patients and health care personnel [113]
• Institute automatic stop orders to remove IUCs or nurse-driven protocols with criteria for insertion and removal when indications are no longer met	• A systematic review and meta-analysis [119] of 14 studies in 2010 found that CAUTI rates decreased 56% with physician and nurse reminders and prewritten stop orders to discontinue catheters • CAUTI rates decrease when physician and nurse reminders and prewritten stop orders and/or nurse-initiated discontinuation of catheters are implemented [120–124]

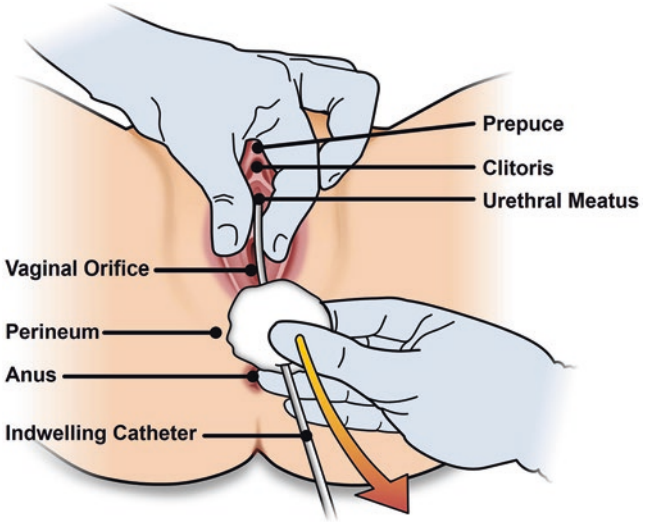


Fig. 1.40 Catheter cleaning—Courtesy of Diane Newman

Table 1.12 Trial of voiding (TOV) or voiding trial or trial without catheter (TWOC) procedure [109–112]

Definition:
Procedure to assess a patient's ability to independently void and fully empty the bladder following IUC removal. Two methods have been identified:
Passive: Allows the bladder to fill naturally
Indication: Preferred method used in acute care following IUC removal (e.g., postoperative urinary retention)
Advantages: Shown to decrease acute care length of stay, eliminate the need for straight catheterization, decrease the potential for developing a CAUTI, decrease incidence of urethral trauma, and increase the accuracy of assessing UR
Active: 30-min procedure where the bladder is filled retrograde with a specific volume of water or saline
Indication: Method commonly used in urology practices for non-urologic patients referred and assessing bladder emptying following urologic procedures
Advantages: Rapid assessment of bladder emptying

Pre-procedure:
- Prior to any contact with the catheter and drainage system, perform hand hygiene and don gloves
- Initiation of alpha-blocker drug therapy may facilitate voiding in some patients with urinary retention. Such medication is started prior to catheter removal. Options include tamsulosin 0.4 mg daily, alfuzosin 10 mg daily, silodosin 8 mg daily, or doxazosin 4 mg daily

Procedure:
- *Passive (also referred to as "autofill"):*
  1. Gather equipment: 10 cc syringe to deflate the balloon and a measuring hat or container to measure voided volume
  2. Disconnect the catheter from the drainage tube
  3. Deflate the balloon ensuring total volume in balloon has been removed
  4. Remove catheter and discard
  5. Empty drainage bag and document amount emptied and time of catheter removal
  6. Push oral fluid intake (if medically appropriate) to allow the bladder to fill naturally
  7. Prompt patient to void when experiencing a strong urge to void but no later than 4 to 6 h after catheter removal following an algorithmic approach to bladder management (see Fig. 1.38)

Active (referred to as the "infusion method" or "backfill voiding trial"):
1. Gather equipment: 60 mL catheter-tipped (Toomey) syringe with plunger (e.g., sterile irrigation tray), room-temperature sterile normal saline solution (300–400 mL), 10 cc syringe to deflate the balloon, non-sterile gloves), and a measuring hat or container to measure urine volume
2. Pour sufficient volume (usually approximately 300 cc) of saline in the irrigation set and draw-up approximately 60 cc of fluid into the 60 mL syringe and place syringe within easy reach
3. Deflate the balloon ensuring total volume in balloon has been removed
4. Disconnect the catheter from the drainage tube and place the 60 mL catheter-tipped syringe into the drainage funnel of the catheter
5. Slowly and gently instill saline in 60-mL aliquots into the bladder through the catheter.
6. Ask patient to report various sensations experienced during filling and note the volumes at which these sensations occur.
   - If a patient reports a strong urge to void at a low instillation volume (e.g., <100 ccs), stop and wait for the sensation to subside. Then restart instillation slowly. The amount to instill is based on clinical judgment and patient assessment.
   - Urge sensation may occur in the following manner:
     a. First desire to void (normally experienced between 100–250 mL)
     b. Normal desire to void (usually between 300–400 mL)
     c. A strong or "must" urge or desire to void (usually occurs between 400–600 mL)
        - Note that volumes listed above are guidelines only and patients will report these sensations at widely varying volumes.

(continued)

Table 1.12 (continued)

- Stop instilling fluid at any time if the patient complains of discomfort or pain.

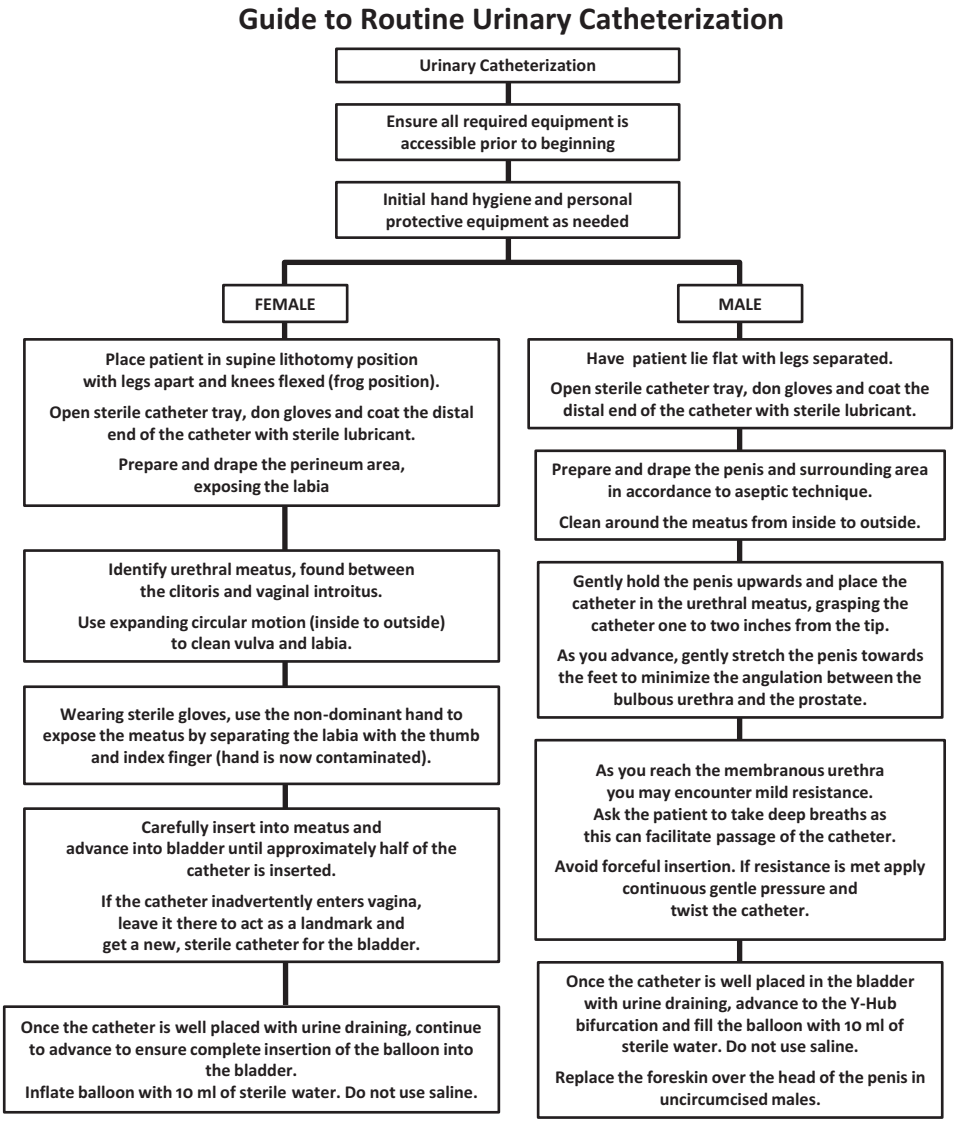
7. Expulsion of the fluid around the catheter or actual expulsion of the catheter suggests a spontaneous bladder contraction (bladder overactivity) which may indicate that the patient will experience) urine leakage when the catheter is removed
8. When the patient reports a strong urge, deflate the balloon (if not already deflated before instillation), immediately remove the catheter, and have patient urinate in a measured container within 15 min
   - PVR is indirectly determined by subtracting the voided volume from the total volume of instilled fluid
9. Scan bladder after patient urinates to determine PVR and adequate voiding (Follow Bladder Management Pathway Fig. 1.38)

Used with permission: Diane K. Newman, DNP

Patient Information

- *Care and Use of an Indwelling Urinary Catheter Patient Education Tool*

Appendix 1: Guide to Catheterization



Source: Adapted from the Society of Urologic Nurses and Associates 2015 Clinical Practice Guidelines: Adult Female Urethral Catheterization & Adult Male Urethral Catheterization

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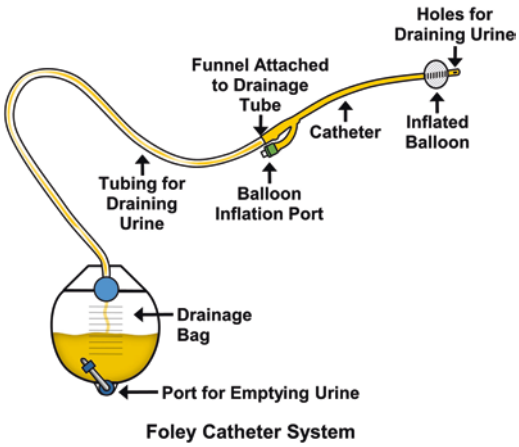
Care and Use of an Indwelling Urinary Catheter Patient Education Tool

What Is an Indwelling Urinary Catheter?

A catheter is a soft hollow tube that drains the urine from your bladder. The catheter, often called a Foley, has a small balloon near the tip, which is filled with water to help hold it in place. The balloon sits at the bottom of your bladder and keeps the catheter tube from falling or being pulled out. The catheter is attached to a long tube that carries the urine to a *drainage bag*, which collects the urine. There are two types of drainage bags, a larger "overnight" bag that can be hung on the side of your bed during the night, and a smaller "leg" bag that is used during the day since it can be fastened under your clothes, hidden away. Once the catheter and bag are put in place, it is a *closed system* and should never be opened unless you are told to do so by your doctor or nurse. The catheter is made from latex or other materials, such as silicone. Catheters must be prescribed by a prescribing clinician and are usually changed by a nurse.

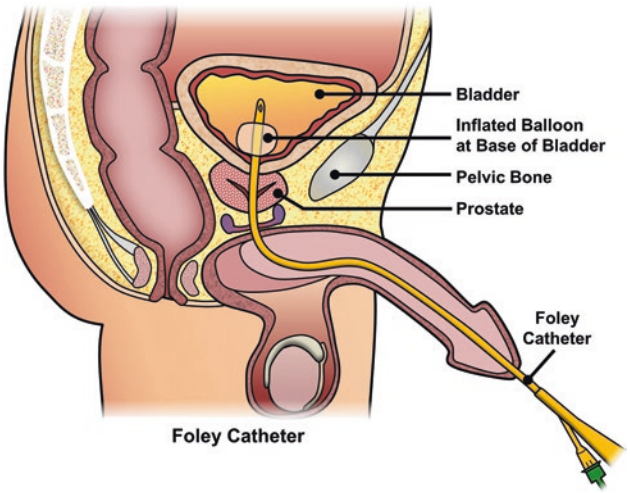


Foley Catheter System

Why Do I Need an Indwelling Catheter?

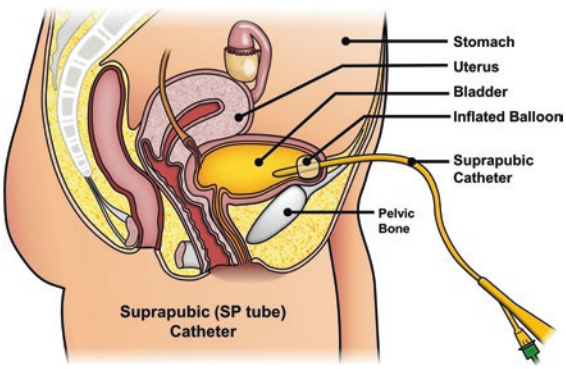
Some people need help to empty urine from their bladder because of certain medical problems that do not let the bladder empty completely. If this happens, a tube called a catheter is put into the bladder to drain the urine. The catheter can be put in your bladder in one of two ways:

The most common way to put a catheter in the bladder is through the urethra (the urethra carries urine from your bladder to the outside). The picture to the right shows a catheter that has been placed through the urethra of a man. The balloon is inflated and sits at the bottom of the bladder.



Foley Catheter

A second way is through an opening or hole made in your lower stomach, above your pubic bone. This catheter is referred to as a suprapubic catheter or "SP tube." The picture to the right shows a catheter that has been placed through the stomach, above the pelvic bone and into the bladder of a woman. The balloon is inflated and sits at the opening into the bladder.



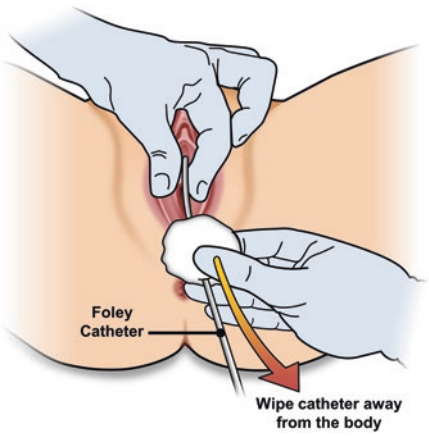
Suprapubic (SP tube) Catheter

How Does a Catheter Feel?

You may sometimes feel burning or spasms when urine passes through the catheter. This is normal, so don't be alarmed. The spasms may cause some urine to leak out around the catheter. If the leaking does not stop, call your doctor or nurse. You may be prescribed medication to stop the spasms. Spasms may also be a sign that the catheter needs to be changed.

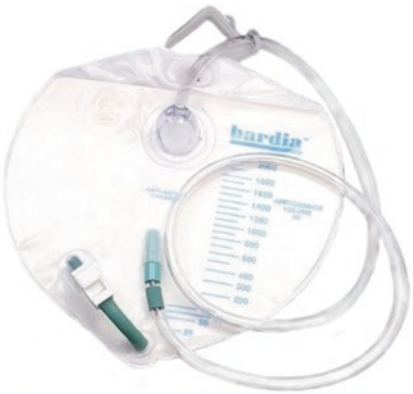
How to Care for Your Catheter?

ALWAYS wash your hands before and after touching the catheter, tube, or bag. You can wash the skin around the catheter with a liquid soap and water every day and after you empty (move) your bowels. You can also wash the part of the catheter that is outside the body. You can use antibacterial soap for washing. As shown in the picture to the right, start cleaning where the catheter leaves the body and clean along the catheter for about 6 in. with mild liquid soap and water. You may notice dried, crusted material on the catheter where it leaves your body. This can be washed away by gently wiping with a wet cloth.



How to Position Your Catheter and Drainage Bag

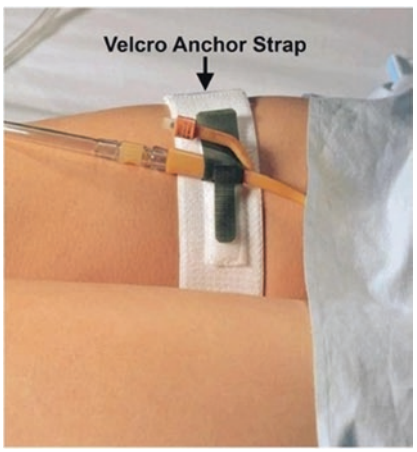
Your catheter will be connected to a drainage bag. You can use either a small leg bag or a large bag at night, when you are asleep. When you go to bed, hang the night bag on the side of your bed or put it in a small wastebasket lined with a clean plastic trash bag next to your bed. The picture on the right is a large bag. Keep drainage bags below the level of the bladder at all times. Avoid kinks or loops in the catheter and tubing that could stop the flow of urine. You should empty the bag at least every 4–6 h or if when it is half filled.



Large (overnight) drainage bag

Securing the Catheter

As shown in the picture to the right, the catheter should be attached to your upper thigh by a strap. An SP tube should be taped or secured to your stomach with an adhesive holder. With both types, leave some slack on the catheter to prevent tension on the bladder.



How to Prevent Infections

Drink plenty of non-alcoholic liquids daily (at least 6–8 glasses, 8-oz size), unless your doctor or nurse tells you otherwise. Liquids include water, tea, coffee, ice cream, sherbet, fruit juice, Popsicles, Kool-Aid, lemonade, and the like. Take 500–1000 mg of vitamin C (true ascorbic acid) two times a day, or drink three 8-oz glasses of cranberry juice, or take two 500 mg cranberry pills each day.

Can I Have Sex with the Catheter in My Bladder?

Sexual intercourse with a catheter in place may require some adjustment. Several women said that they position the catheter to the side and make sure that the tubing is out of the way.

What to Do and What Not to Do

1. **Do**—drink enough liquids during the day as this will help keep fluids moving through the catheter and prevent infection. Keep glasses of water or a jug of water around the house, near you.
2. **Do**—wash your hands before and after emptying or changing drainage bags.
3. **Do**—shower if you have a catheter. Keep the drainage bag connected to the catheter while in the shower.
4. **Do Not**—use alcohol to wash the catheter or skin around the catheter as this can be irritating, sting and cause the skin to dry.
5. **Do Not**—pull on the catheter, tubing, or bag and never pull out the catheter yourself.
6. **Do Not**—disconnect any part of the catheter system unless your doctor or nurse has allowed you to use a leg bag during the day and an overnight bag at night. If the tubing becomes disconnected, clean the ends with an alcohol-soaked pad and reconnect it immediately. Then call your doctor or nurse, because the catheter may need to be changed.
7. **Do Not**—irrigate the catheter, unless told to do so by your doctor and unless you have been shown the correct way to do it. If it becomes clogged and stops draining, call your doctor or nurse.
8. **Do Not**—be alarmed if the catheter sometimes leaks. This is normal and is caused by bladder spasms. It is only a problem if no urine is draining.

Call Your Doctor or Nurse if:

- The urine has a strong smell, becomes cloudy or dark, or turns red.
- You have chills, a fever above 100ºF, lower back pain, weakness, and/or leakage around the catheter.
- There is swelling at the place where the catheter is inserted.
- There is an increased amount of sediment in the drainage tube or bag.
- The catheter is not draining any urine (first make sure the catheter or tubing is not blocked or kinked).
- The catheter falls out. *If you have an SP catheter and it falls out, you must call your doctor or nurse right away so it can be replaced.*

Catheters Used for Intermittent Catheterization

2

Lance L. Goetz, Linda Droste, Adam P. Klausner, and Diane K. Newman

Definition

Intermittent catheterization (IC) is a manual bladder-emptying technique. Either the patient or a caregiver inserts a catheter via the urethra, drains the bladder, and removes it once all urine is drained. IC usually occurs 4–6 times a day. This method of catheterization is an effective long-term bladder management strategy for individuals who have urinary retention or in those patients with incomplete bladder emptying. IC can be performed by patients of different age groups, including older adults and children starting from 4 years old under parental supervision. It offers the patient the ability to maintain independence because the patient has the choice of when and where to empty the bladder and perform bladder self-care.

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Indications: (Urinary Retention and NLUTD)

Bladder management in neurogenic lower urinary tract dysfunction (NLUTD) requires an understanding of lower urinary tract pathophysiology, critical to developing an optimized plan for long-term management. The goal is to ensure complete bladder emptying before the occurrence of high-pressure, uncoordinated involuntary detrusor contractions and other complications.

Symptoms of NLUTD include urinary incontinence (UI) or incomplete bladder emptying caused by outlet obstruction, ineffective detrusor contractions, or decreased compliance. Draining the bladder at regular intervals throughout the day reduces bladder pressure and improves circulation to the bladder, thus making the bladder urothelium more resistant to infectious bacteria [1].

Lower urinary tract symptoms (LUTS) are common in patients with neurologic disorders or conditions with neurological complications. NLUTD is prevalent in the spinal cord injury (SCI) population (50–80%), but severity of LUTS depends on the level and completeness of spinal cord involvement. Twenty percent of SCI patients have been identified as having urinary retention and 25% have been diagnosed with detrusor sphincter dyssynergia, which can lead to incomplete bladder emptying. The actual number of SCI patients who have these symptoms is likely higher.

Intermittent catheterization remains the treatment of choice for many patients with difficulty emptying their bladder due to neurogenic and non-neurogenic causes because it is widely available and minimally invasive [2]. IC has become the standard of care for persons with SCI and NLUTD who have adequate hand function or caregiver support. According to the Neurologic Urinary and Faecal Incontinence Committee 10 of the Sixth International Consultation on Incontinence 2017, "the mainstay of treatment in current practice is IC undertaken by the patient or carer" and is the treatment of choice where there is a significant post-void residual (PVR) [3]. A major goal of an IC program is to ensure complete bladder emptying

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before the occurrence of high-pressure, uncoordinated, involuntary detrusor contractions. This requires a team approach involving educators, clinicians, therapists, social workers, and family members or caregivers [4]. The bladder management plan should be continually adjusted based on evolving patient needs and circumstances.

Although patients may follow a set schedule for performing self-catheterization, an increase in fluid intake can change intervals between catheterization. Thus, when patients or clinicians ask about the correct timing for performing IC, these individuals should be redirected to think about bladder management in terms of appropriate volume intervals. Catheterization should be timed such that the bladder is emptied before the volume at which high-pressure involuntary bladder contractions develop. Conversely, however, persons on an IC program must not go for a prolonged period without emptying the bladder, as urine stagnation and heavy bacterial growth can occur.

Methods

Clean intermittent self-catheterization (CISC), also referred to as intermittent self-catheterization (ISC), clean intermittent catheterization (CIC) or intermittent catheterization (IC) are bladder management techniques used to drain urine from the bladder with subsequent immediate removal of the catheter once all urine is drained [5]. CISC requires the patient performing the catheterization use clean technique (no gloves), ordinary hand washing or hand sanitation with prompt removal of the catheter. The patient should use a single-use (disposed after use) catheter as multiple-use (reused for multiple catheterizations) cleansed catheter is no longer recommended. Ensuring patient adherence to ISC techniques is imperative for prevention of long-term complications [6]. Patients must remain vigilant in the use of clean technique and must catheterize ("cath") at intervals sufficient to avoid elevated bladder pressures (reducing the risk of vesicoureteral reflux and subsequent damage to the kidneys) and to prevent urinary leakage. Contrary to the hospital and institutional settings, where sterile technique is mandated, clean technique is the standard of care for persons living in the community [1].

The International Continence Society defines CISC as the use of a clean technique to drain the bladder with subsequent removal of the catheter performed by the patient. Clean technique implies the use of a clean technique and involves ordinary washing/cleansing techniques, and the use of disposable catheters [7]. Table 2.1 provides terminology used for IC [2, 5]. Shamout and colleagues [8] note that even with guidelines from international professional organizations, most clinicians use "their clinical judgment to determine which technique and type of catheter to use."

History of Intermittent Catheterization

The technique of sterile IC was first used following World War II by Sir Ludwig Guttmann, in the bladder management of SCI patients. Guttmann and Frankel [7] proposed that routine bladder emptying was more physiologic and would provide better outcomes than indwelling catheters.

In 1972, urologist Dr. Jack Lapides introduced clean intermittent catheterization, since referred to as CIC, as a safe method of bladder emptying with low infection incidence. Dr. Lapides described a nonsterile technique for reusing a catheter for multiple catheterizations that involved sterilization of the catheter by soaking for 20 minute (min) before reuse.

IC is the preferred method of bladder management in the SCI population with LUTD and other conditions that cause incomplete bladder emptying [9]. IC is often referred to as the gold standard and is used to protect the bladder and kidneys by preventing over distention and urinary tract infections (UTI).

IC is favored over indwelling urethral or suprapubic catheters (IUC) because of evidence that it decreases the incidence of urinary tract infection (UTI) [10, 11]. IC has also been found to be associated with a lower occurrence of candiduria [12].

IC is considered a safe procedure with a lower rate of certain complications such as penile trauma and traction injuries or traction hypospadias, as compared to an IUC [11]. Ercole et al. [13] reported that CIC was associated with lower rates of UTI and complications of the lower urinary tract when compared to an indwelling catheter. The study also found a lower incidence of UTIs when sterile IC was compared to clean technique (see Table 2.1 for definitions of sterile and clean technique).

IC may be performed using sterile technique, but clean technique (CIC) is more commonly used. IC should be performed every 4–6 hours (h). Persons with spinal cord injuries and disorders (SCI&D) using IC need to catheterize frequently enough to keep volumes lower than predetermined levels defined by urodynamic studies. Generally, the urodynamic goal is a storage pressure lower than 40 centimeter (cm) H_2O [14]. Further studies are needed to determine the relative importance of management variables in influencing the rate of UTIs for those who perform IC.

IC is not for everyone, and a patient must first be assessed to determine if he or she is a good candidate. Assessment should determine if the person has a suitable bladder capacity and sufficient arm and hand dexterity, vision, cognition, and motivation to carry out the procedure [14]. In an IC program, the bladder acts as a reservoir for urine, so it is important that the person has reasonable bladder capacity. The greater a patient's ability to store urine at safe pressures and without leaks, the greater chance the person has of success with IC. Adults who have small bladder capacity

Table 2.1 Intermittent catheterization terminology and definitions

Terminology	Definition
Sterile	• Usual technique in environments such as hospitals, use of sterile catheterization tray or kit that includes: sterile gloves, genital disinfective, single-use catheters, sterile drainage collector
Aseptic	• Use of sterile gloves, single-use catheter, preceded by disinfecting the genitalia with an antiseptic solution, and without direct manual contact with the catheter (e.g., no touch technique, sterile lubricant or pre-lubricated catheter)
Intermittent self-catheterization (ISC)	• Implies the patient is catheterizing on a schedule determined by drained bladder volume • A single-use catheter (e.g., external lubricant or pre-lubricated gel, hydrophilic) with a non-antiseptic solution for cleaning hands and perineum • If a single-use catheter is reused, there is no evidence-based research on the best method for cleaning and storing the catheter between uses • If a caregiver (parent catheterizing a child) is performing the catheterization gloves are used
No-touch	• Sterile all-inclusive type of catheter system inside a protective sleeve or collection bag or product packaging may be used to hold the catheter during insertion • No additional supplies are needed for sterile catheterization technique
Clean catheterization	• Technique that implies hand washing with soap and water, and cleansing the genitalia only if fecal or other wastes are present • If a caregiver (parent catheterizing a child) is performing the catheterization gloves are used

(100–200 milliliter (ml)) are not usually considered suitable for IC [14, 15]. IC requires a commitment to catheterize up to 6 times a day or more if needed. The person has to be dedicated to IC and must carry catheters and associated supplies when away from their home. IC takes longer than simply voiding, and the person may develop infections, bleeding, or trauma. Women who are chair fast (e.g., in a wheelchair) may find the procedure difficult or spill urine when catheterizing [14], so male length catheters or those with integrated bags could be considered in those cases.

Advantages of Intermittent Catheterization

Optimal management of the lower urinary tract is important in patients with NLUTD to prevent damage to the upper urinary tract and preserve renal function. Intermittent catheterization can be a practical and effective method of bladder management and is usually performed by the patient or their caregiver. Advantages of IC include avoidance of complications that can occur with indwelling catheters. These include: catheter-related trauma, urethral traction injury/hypospadias, and dilation of the bladder neck with subsequent leakage at low pressures. IC eliminates the need for tubing, leg bags, or bedside drainage bags and creates the freedom to wear shorts or skirts without exposed devices. IC has a lower risk of bladder stones or cancer than with an indwelling catheter. Not having a catheter in the urethra is also an advantage for persons who wish to be sexually active.

Characteristics of Intermittent Catheters

There are a wide variety of urinary catheters available including: uncoated polyvinyl chloride (PVC) that needs a separate lubricant for manual application (see Fig. 2.1), gel-coated (pre or self-lubricating) PVC (see Fig. 2.2), and hydrophilic-coated (HC) catheters. HC catheters includes those that require manual activation through addition of water or salt solution or those where the catheter comes ready-to-use, either coated with solution or with solution in a sachet in the package (see Fig. 2.3a) [16]. Catheter selection is dependent on insurance coverage, availability, and patient/caregiver preference. However, catheter type and/or material may be important for patient compliance with IC, which is required if the benefits are to be realized. With a long-term management strategy like IC, patient satisfaction is crucial, as it influences adherence to the IC regimen.

Fig. 2.1 PVC single use catheters that require external lubricant. (**a**) *Apogee*® Short length straight tip—Courtesy of Hollister. (**b**) *Apogee*® Long length straight tip—Courtesy of Hollister Inc. (**c**) Long length with Coudé tapered tip—Courtesy of C.R. Bard, Inc.

Fig. 2.2 Catheter is passed through a self-lubricating reservoir at tip—Courtesy of Hollister Inc.

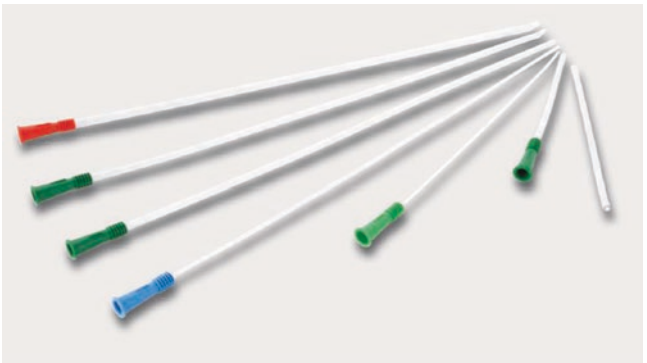


Fig. 2.4 Male (long) and female and pediatric (short) catheters—Courtesy of Hollister, Inc.

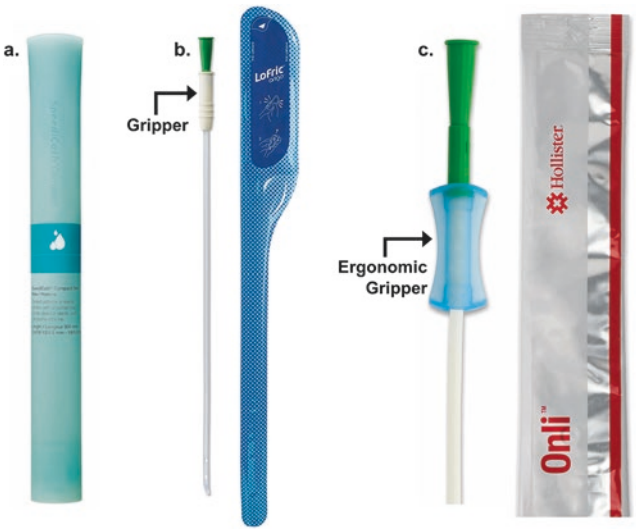


Fig. 2.3 (**a**–**c**) Single-use HC catheters (**a**) Compact "no-touch" design with an integrated bag, also comes in female short length—(SpeediCath® CompactSet™)—Courtesy of Coloplast Corp. (**b**) "No-touch" catheter (12 in., 16 in. length, straight or Coudé tip) with packages, coated with Urotonic™ Surface technology, salt solution coating is activated with a gentle squeeze, easily foldable into a small pocket size (LoFric® Origo™)—Courtesy of Wellspect HealthCare. (**c**) Ready to-use HC (16 in.), reduced spill with short (7 in.) and long (16 in.) lengths (Onli™)—Courtesy of Hollister Inc.

The characteristics of catheters used intermittently are similar to IUCs (see Chap. 1) and are described below. Types of catheter material are discussed later in this chapter.

Catheter lengths for IC are gender specific, with male, female and pediatric lengths available to accommodate the length of the urethra. Standard male catheter length is 16″ (~40 cm), whereas female catheters range in length from 6–12″ (see Fig. 2.4). Pediatric catheter lengths are 6–10″. Many women find that shorter catheters do not shift and are easier to grasp and insert (see Fig. 2.5a, b) [1]. The funnel colors of the newer female short catheters may not indicate the size. Catheters are sold individually packaged and some require the addition of lubrication. Catheter lengths can now accommodate more compact designs that are discrete and can be easily carried in a purse or pocket (see Fig. 2.6a–d) [12]. Chartier-Kastler and colleagues [17] reported on a randomized, 2-way crossover, multicenter study in patients with NLUTD (n = 125) that evaluated discreet design compact HC catheters compared to standard catheters. The study showed 63% of patients preferred compact HC catheters because of their positive effect on quality of life.

Catheter diameter is measured in French (Fr) units, similar to the size of IUC diameter. Sizes range from 6 to 12 Fr for children and 14 to 22 Fr for adults. The funnel end of the catheter is often color coded to allow for easier size identification (see Fig. 2.7).

Catheter tips are curved and tapered (Coudé/Tiemann/Olive tip) or straight (see Fig. 2.8a, b). They are most often referred to by the generic term Nelaton (after Auguste Nelaton, inventor of the Nelaton rubber catheter) (see Fig. 2.9). This is often the catheter that patients will begin to use during their

initial transition to IC [18]. A Coudé or Tiemann tip intermittent catheter is firmer and curved at a slight angle to assist in navigating of the male urethra (see Fig. 2.8b). The curve is tapered to the tip. The shape and stiffness of the catheter help to ease the passage through the bladder in patients with an enlarged prostate. Carson and olive tipped catheters (see Fig. 2.10) have a slightly larger bulb at the end that may assist in negotiation of a urethral stricture or to assist female patients in locating the meatus [1].

Catheter drainage openings ("eyes" or "eyelets") are placed on one side or on opposing sides of the tube (see Fig. 2.11). Opposing drainage eyes generally facilitate better drainage. Some patients have problems with sediment or mucus that can clog the drainage eye and larger openings may be needed. Catheters have been designed with smoother eyelets, either polished or ultrasonically smoothed eyelets to minimize urethral abrasion during passage.

Fig. 2.5 14 Fr Female adult and pediatric short length catheters. (**a**) HC catheter with straight tip, salt solution sachet and larger funnel end that allows for better grip (LoFric® *Sense*™)—Courtesy of Wellspect HealthCare. (**b**) Female catheter with straight tip (*Magic*[3]® *Go*)—Courtesy of C.R. Bard, Inc.

Although IC has decreased the incidence and severity of UTIs in hospitalized patients, hospital acquired gram-negative organisms in the urine, many of which are resistant to antibiotics have become a major concern. Catheter-associated UTIs (CAUTI) remains the most common hospital acquired infection (HAI) [19]. Such infections result in increased morbidity, loss of patient therapy time, prolonged hospital stays, and increased rehabilitation costs [20]. Healthcare facilities have gone to great lengths to reduce the incidence of CAUTI, driven by denials in reimbursements from insurers.

Introducer tips are preferred by some clinicians for certain patients. Many systems are catheters enclosed in a bag with a urethral introducer tip (see Fig. 2.12) that protects the catheter from contamination as it passes through the first 1.5 cm of the urethra, where larger numbers of microorganisms are present [21, 22]. This portion of the distal urethra can be colonized with perineal bacteria, particularly *E. coli*. Colonization with other pathogens, such as *Pseudomonas* and *Klebsiella* species, frequently occurs in the perineum and urethra of men with a SCI (see Fig. 2.13a–c Introducer tips instructions).

The MMG/O'Neil catheter (Medical Marketing Group) was the first example of an intermittent catheter system with an introducer tip (see Fig. 2.14). It was originally developed in Australia in 1982 for use in obstetric patients, but has been tested in acute and rehabilitation settings on SCI patients. Other manufacturers have incorporated introducer tips in their products.

Catheter Reuse

Reuse of catheters for IC is controversial Manufacturer guidelines state that a catheter designed for intermittent drainage of the bladder is single-use and is to be discarded

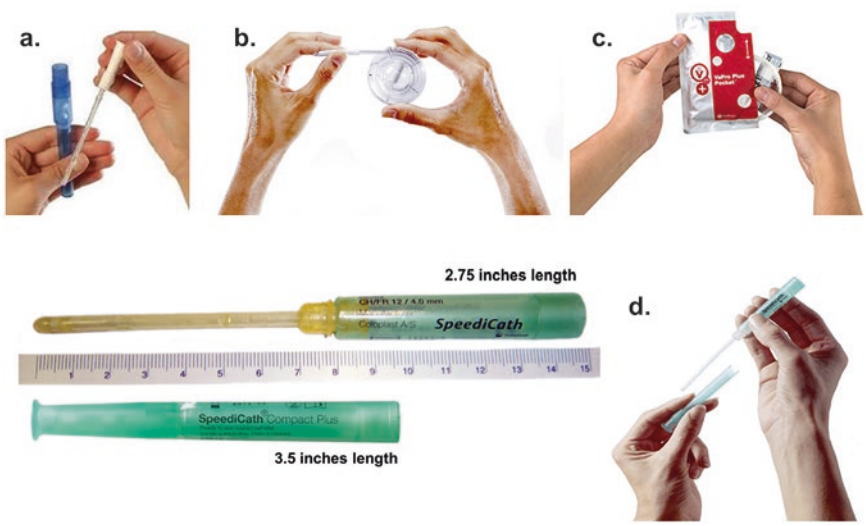


Fig. 2.6 (**a**–**d**) Small discrete packaged, pocket/compact catheters. (**a**) Short catheter (Twist®)—Courtesy of Cure Medical. (**b**) Catheter coiled around a case, "no-touch" as passed through a sheath, cooled back in case when done (Compact Cath). (**c**) Pocket "no-touch" catheter (VaPro® Plus Pocket)—Courtesy of Hollister Inc. (**d**) Compact 2.75 in. length female (SpeediCath®) & 3.5 in. length female (SpeediCath® Plus)—Courtesy of Coloplast, Corp.

Fig. 2.7 Catheter funnels: color-coded French (Fr) size—Courtesy of Hollister Inc.

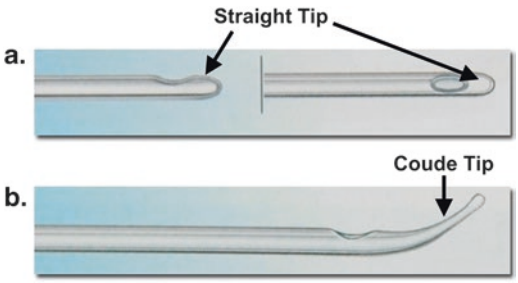


Fig. 2.8 Catheter Tip configurations (**a**) Straight tip (**b**) Coudé tapered tip

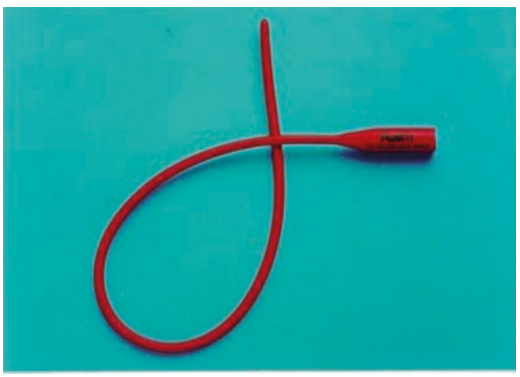


Fig. 2.9 Nelaton red rubber catheter—Courtesy of C.R. Bard, Inc.

Fig. 2.10 Olive Coudé Tip with eyelets repositioned to the sides of the catheter and a blue Guide Stripe® along the top of the catheter allows the patient to monitor correct position of the Coudé tip throughout catheterization (*Self-Cath*® Plus)—Courtesy of Coloplast Corp.

Fig. 2.11 Offset eyelets on catheter tip

Fig. 2.12 Gel-based catheter with introducer tip (Advance Plus)—Courtesy of Hollister Inc.

after use. According to the US FDA, all sterile urethral catheters are single-use devices and not approved for reuse. Many patients and providers argue that there is a theoretical increased infection risk if a catheter is reused. Despite the wide use of IC, two Cochrane reviews [23, 24] noted that there are no definitive studies showing improvements in the incidence of UTI by catheterization technique, type, or strategy. Data are also lacking for recommending a cleaning method for multiple-use catheters. However, one of these reviews has recently been withdrawn [24] and their findings have been questioned [http://online.liebertpub.com/doi/pdfplus/10.1089/neu.2017.5413]. The most recent guidance from Infectious Disease Society of America also rated the evidence for multiple-use as poor [25].

Moore et al. [26] found that 87% of patients (62/71) cited concerns over infection as the main reason for refusal to reuse catheters. Since 2008, single-use, disposable catheters for ISC has become the standard in the US as health insurers and providers, including Medicare and the VA system have changed reimbursement to allow the purchase of single-use catheters. Medicare, now allows purchases of up to 200 catheters per month [2].

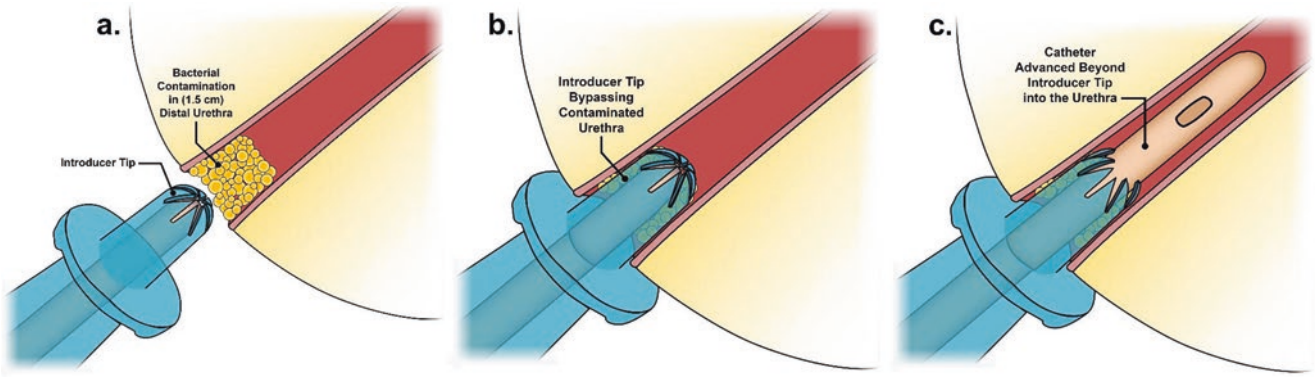


Fig. 2.13 (**a**–**c**) To bypass the distal urethra area, the catheter is advanced into the introducer tip, the tip is inserted into the distal urethra, and then the catheter is passed through the tip into the urethra. This prevents contamination of the catheter and introduction of bacteria into the bladder

Fig. 2.14 Original introducer tip closed "No touch" catheter system—Rusch MMG

This is also the case in other countries but reuse after cleansing may be the only option in certain circumstances (e.g., lower income countries) [27]. Health care providers should advocate a single use of catheters in individuals with SCI, especially as there is no standardized or universally accepted cleaning method [http://online.liebertpub.com/doi/pdfplus/10.1089/neu.2017.5413]. If UTIs become problematic in an individual reusing a catheter, he/she should be encouraged to use a new catheter each time.

In patients on IC, bacteriuria is more likely caused by ascending bacteria into the bladder colonizing the urethra, than introduction of new bacteria [14, 25]. Rinsing with water, microwaving, boiling or soaking catheters in various agents and then air-drying are all thought to be effective in reducing bacteria on catheters. However, there are no published trials evaluating the effectiveness of any of these cleaning-methods in preventing bacteriuria or CAUTI [28]. Many experts discourage microwaving and boiling catheters as increased temperatures may alter properties of the catheter.

Closed vs. Open System Catheters

Currently, no high-level evidence demonstrates sterile technique as superior to clean technique for reducing CAUTI. Likewise, no evidence has demonstrated closed or pre-packaged catheter kits containing all accessories (e.g. gloves, –antiseptic, –solution, etc.) (see Fig. 2.15) to be superior to closed self-contained (catheter in the collection bag, tip pre-lubricated) catheter systems (some are referred to as "no-touch" or "touchless") (see Fig. 2.16). Both systems are sterile. Use of the "no-touch" technique (in which the catheter and pre-attached collecting system are not touched by the patient) reduces microbial contamination of the catheter (see Chart 2.1) [22]. There is some evidence that use of sterile prepackaged catheter collection kits can reduce the frequency of UTIs in SCI patients [27, 29]. However, these kits are expensive and insurers require justification for them. At least two CAUTIs in a patient in 12 months would be medical justification for prescribing a sterile catheter kit or closed system [30]. These kits are also justified if the patient is immunosuppressed (e.g. post-transplant), has AIDS, on cancer chemotherapy, documented vesicoureteral reflux and/or resides in a nursing facility.

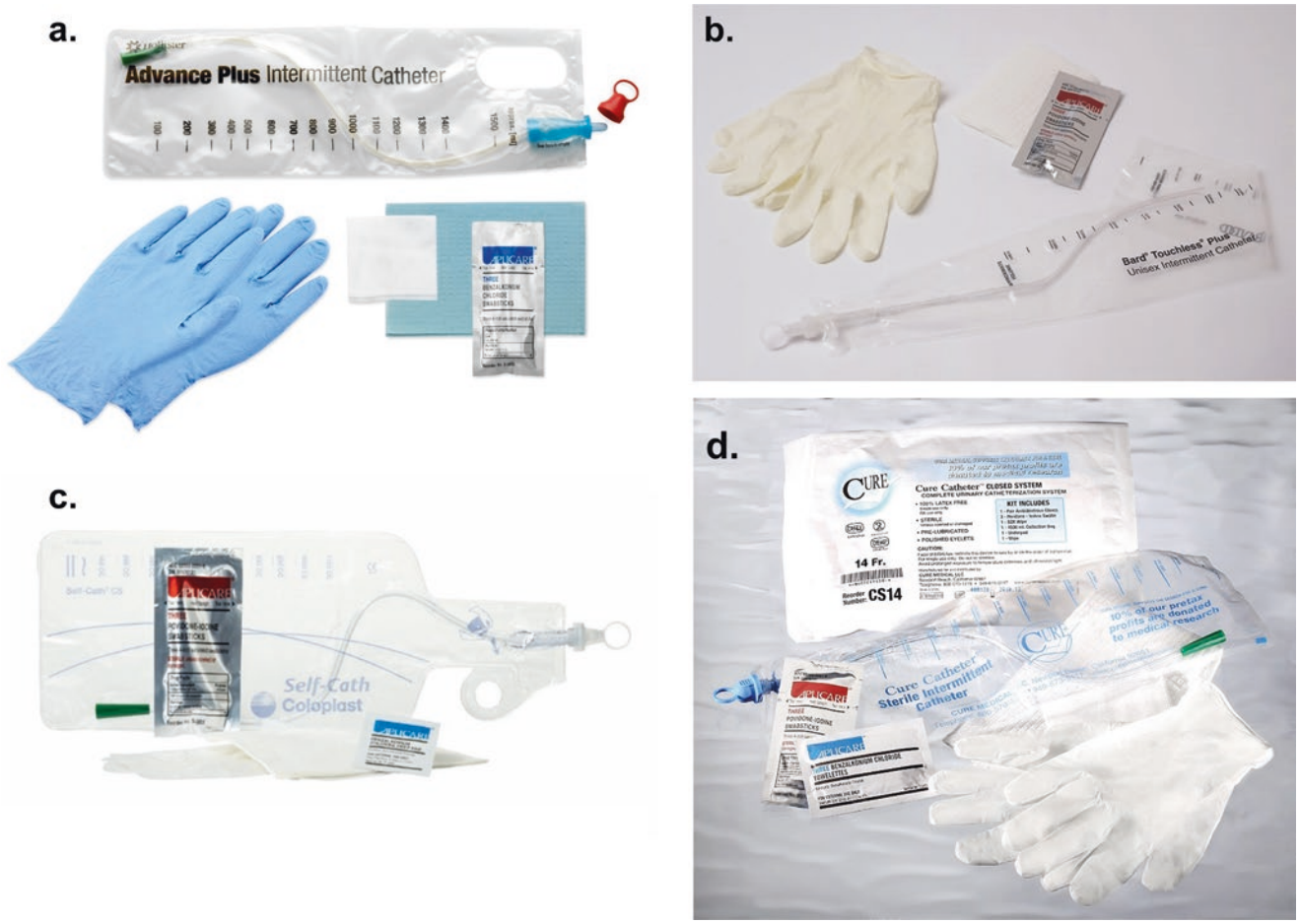


Fig. 2.15 (**a**–**d**) Sterile IC kits with gloves, antiseptic cleanser, lubricant, introducer tip, catheter in drainage bag. (**a**) *Advance Plus*—Courtesy of Hollister Inc. (**b**) *Touchless® Plus* catheter kit—Courtesy of C.R. Bard Inc. (**c**) *Self-Cath* with introducer tip—Courtesy of Coloplast, Corp. (**d**) Cure Catheter™ Closed System—Courtesy of Cure Medical

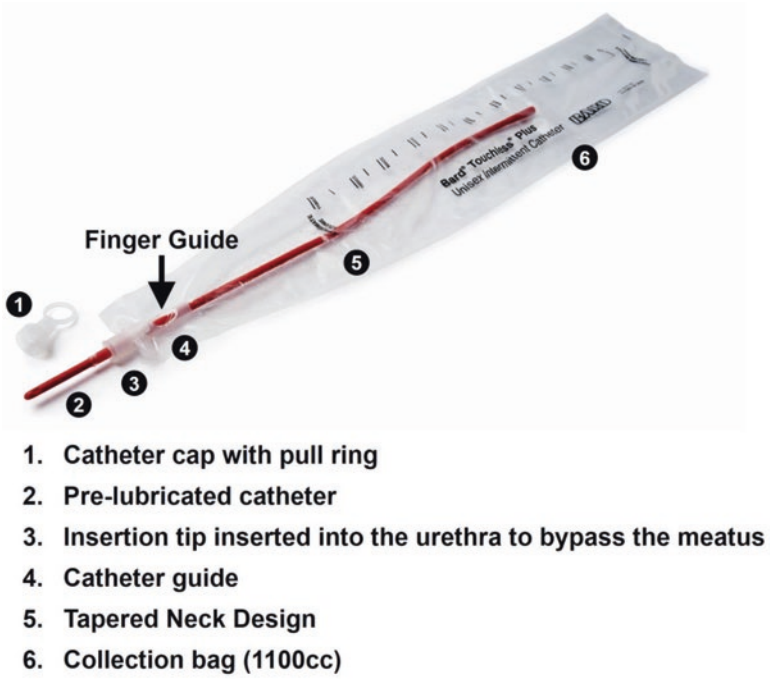


Fig. 2.16 *Touchless® Plus* Catheter system—Courtesy of C.R. Bard, Inc.

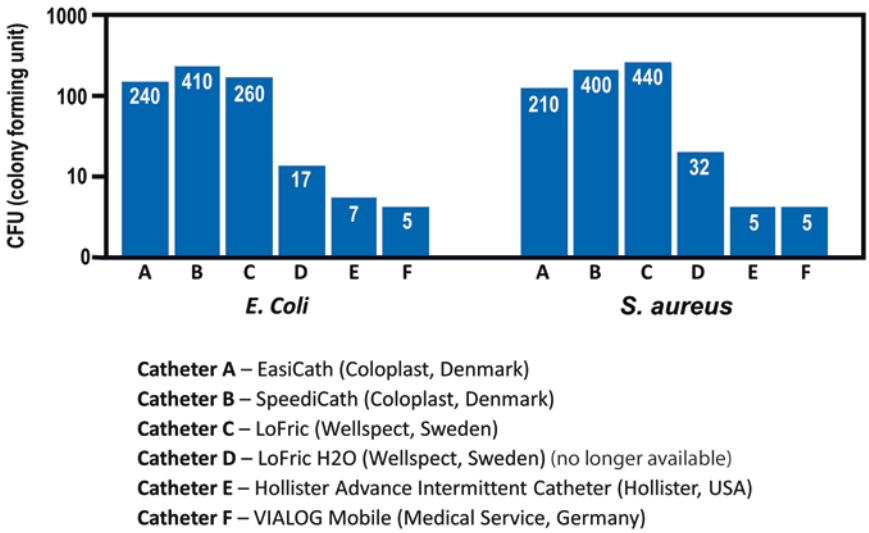


Chart 2.1 "No-Touch" method: reducing bacteria. *Catheter A*: EasiCath (Coloplast, Humlebaek, Denmark), *Catheter B* SpeediCath (Coloplast, Humlebaek, Denmark), *Catheter C*: LoFric® (Astra Tech, Mölndal, Sweden), *Catheter D*: LoFric® H2O (Astra Tech, Mölndal, Sweden), *Catheter E:* Hollister Advance Intermittent Catheter (Hollister, Illinois, US), *Catheter F:* VIALOG Mobile (Medical Service, Bad Liebenzell, Germany). Adapted from Hudson and Murahata [22]

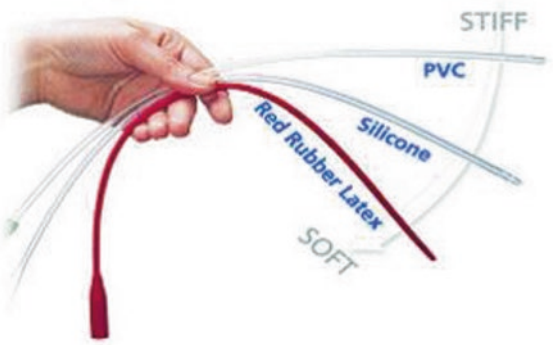


Fig. 2.17 Different catheter material

Materials

Catheter surface material and properties can be important when it comes to UTIs, urethral complications, and patient satisfaction and preference. A number of different polymers are used for the construction of catheters, including PVC, rubber, nylon, and silicone (see Fig. 2.17). PVC is the most common as it is inert and does not react when it comes in contact with bodily fluids. The Nelaton, Coudé/Tiemann, and O'Neil catheters can be made of different types of materials which include red rubber latex, PVC or other plastics, or silicone. One concern with the manufacturing of flexible PVC devices is that plasticizers, such as di-2-ethylhexylphthalate (DHEP), must be added. PVC and DEHP both implicate environmental and health concerns, so alternative materials have been developed. PVC-free catheters are available including polyolefin-based elastomer (POBE), such as the *LoFric*® catheter, used since 2008 [31], and polyurethane tube material of *SpeediCath*®. Catheters made of POBE have lower environmental impact [32]. Although more expensive, silicone catheters have increased in popularity due to increased latex allergies. However, unlike the silicone material used for IUCs, silicone catheters manufactured for intermittent use are softer and more flexible. Some persons may have trouble advancing the softer silicone catheters, while stiffer catheters (e.g. PVC) may cause urethral trauma. One new composite catheter design has three layers, with a soft outer silicone, a stiffer silicone middle layer, and an inner, pliable silicone layer (see Fig. 2.18 M^3 Technology). The design is also available with both hydrophilic and antimicrobial coatings.

Designs

Coated and non-coated are two main designs of catheters used for intermittent bladder drainage. Some catheters are sterile, individually packaged and intended for one-time use (see Fig. 2.19 Individually packaged PVC). But some uncoated catheters, primarily PVC catheters, have been reused, when insurance coverage is not available and cost is a factor [34]. Noncoated catheters require separate external gel lubrication, before insertion. Catheters with a coating and flexibility are self-lubricated and thus are designed to improve catheter lubrication and ease of insertion and, may reduce trauma and UTIs. The most common coating is hydrophilic [35].

Antimicrobial coated catheters: Intermittent catheters, like IUCs, may also be coated with antimicrobial agents. Nitrofurazone and silver are the two most commonly used.

Hydrophilic coated (HC) catheters have become increasingly popular. They were introduced in 1983 to reduce catheter-related complications and have demonstrated the potential to decrease UTIs in persons who use IC for bladder management [36]. HC catheters (discussed later) have a polymer coating that adheres to the catheter surface and becomes slippery and smooth when wet. They were developed with the goal of reducing friction, thereby reducing trauma during

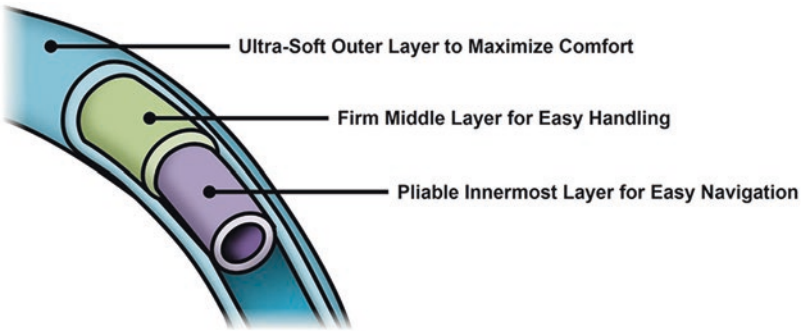


Fig. 2.18 *Magic*$^{3®}$ Technology- 3-all silicone layer—Courtesy of C.R. Bard, Inc.

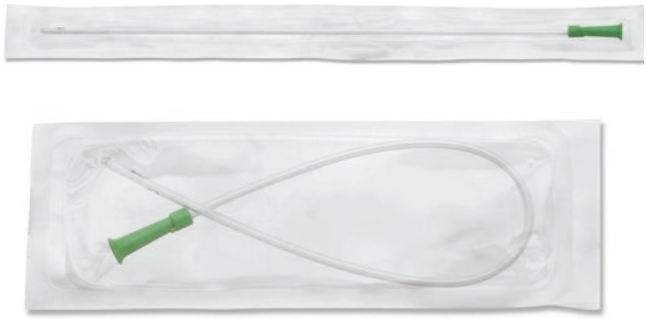


Fig. 2.19 Individually packaged 14Fr PVC non-lubricated single-use Apogee catheter—Courtesy of Hollister Inc.

the catheterization process. HC catheters include those that require the addition of water by breaking or bursting a water packet or salt solution in the packaging which activates the hydrophilic coating (see Fig. 2.20a–c). Prehydrated and ready-to-use HC catheters also exist. Both types of HC catheters remain strictly for one-time use and should never be reused. The lubrication helps to ensure more comfortable insertion and decrease friction and trauma to the urethra. Hydrophilic catheters (see Figs. 2.21 and 2.22) contain a coating made of polyvinylpyrrolidone (PVP), which is a non-allergic material that has been used in medical devices since the 1930s. When exposed to water, the PVP coating attracts water to the surface of the catheters, creating a biocompatible coating that binds water to the surface of the catheter and forms an outer layer mainly consisting of water. This thick, slippery, smooth layer of water stays on the catheter, ensuring lubrication of the entire urethra during the catheter insertion and withdrawal, thereby reducing the coefficient of friction by at least 95%. A recent study compared PVC versus a PVC-free material (POBE) catheter (e.g. LoFric®) [37]. Low rates of discomfort were found with both, but the PVC-free HC catheters had fewer instances of discomfort.

A "touchless" catheter is a one-time use catheter that is either enclosed in a collection bag (see Figs. 2.14, 2.15, 2.16, and 2.20), has a protective sleeve that covers the catheter preventing direct hand contact with the catheer during preparation and catheterization [38] (see Fig. 2.23), or has an insertion aid (gripper) (see Fig. 2.3b, c). This type of catheter is recommended for patients with a history of frequent CAUTIs (e.g. secondary to poor technique). Many use this product when away from home. Although more expensive, these products are generally covered by Medicare and private insurance, if justification and medical necessity is provided.

Gel coated IC kits contain a water soluble gel reservoir or chamber, which provides lubrication as the catheter passes through the gel chamber at the tip of the catheter. This helps to prevent contamination; as direct contact is not needed to apply the lubricant. A disadvantage of these catheters is that they can be slippery and messy, making it difficult for the patient to hold the catheter during insertion.

Noncoated catheters are generally packaged with a separate gel, usually in a foil packet that must be opened and applied directly to the catheter prior to insertion. This requires an extra step, can be messy, and can be difficult to ensure complete lubrication of the entire catheter. Some female patients use only water to lubricate the catheter.

Evidence-Base Research

Hydrophilic coated catheters have been developed with the goal of reducing friction and thereby reducing trauma during the catheterization process. Chartier-Kastler and Denys [39] published a review of experimental and observational evidence, including randomized controlled trials that noted a large body of evidence to support the benefits of HC catheters in patients with NLUTD [10]. This data indicates that HC catheters may be preferable to PVC catheters in terms of safety and quality of life. Most of the research on IC has focused on the *LoFric*® and *SpeediCath*®, and as compared with PVC catheters, include reduced UTIs [10, 40, 41], reduced micro-hematuria [41, 42], and high levels of patient satisfaction [40, 41]. De Ridder and colleagues [40] found, in a randomized 1-year prospective trial in 2005, a statistically significant reduction in UTIs with hydrophilic coated versus noncoated catheters. However, 64% of persons using HC catheters (versus 82% for noncoated catheters) still had one or more UTIs during the study period. Furthermore, there was no significant difference in bleeding, bacteriuria, or pyuria between the two groups. Stensballe et al. [43] found a

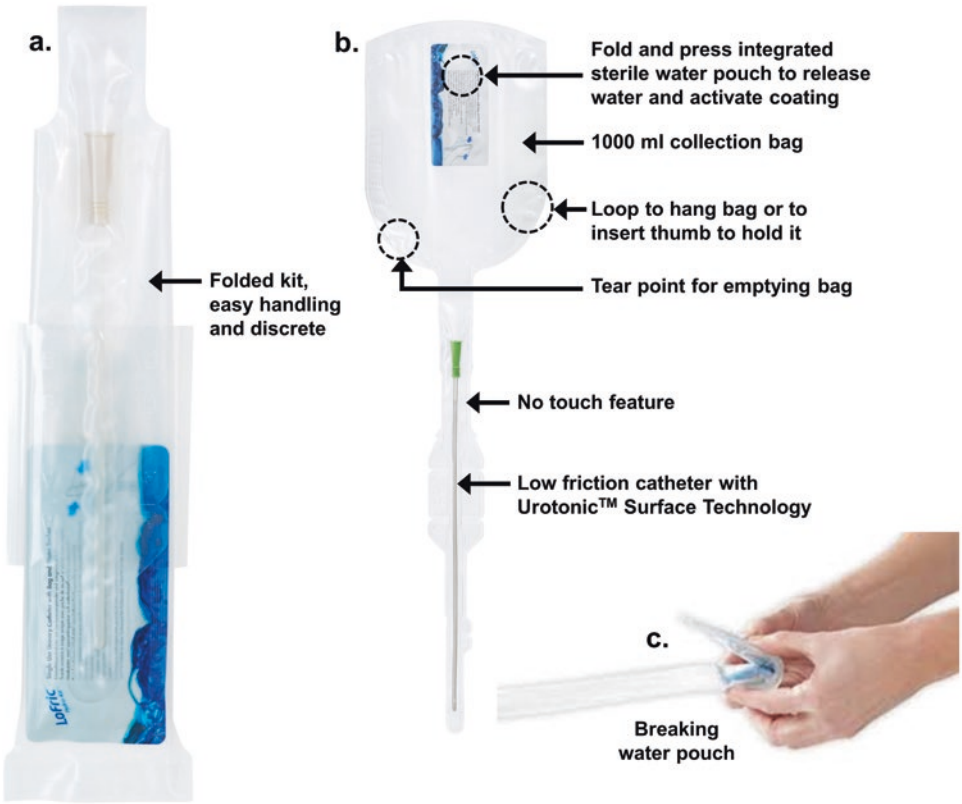


Fig. 2.20 All-in one catheter system with water and an integrated urine collection bag, useful for wheelchair users or bedridden patients. (**a**) Foldable into discreet pocket size, (**b**) Catheter with Urotonic™ Surface Technology activated with salt solution sachet, integrated bag attached, (**c**) Fold and press to activate sterile salt solution sachet. Available in sizes for men, women, and children, straight or Coudé tip. (LoFric® *Hydro-Kit*™)—Courtesy of Wellspect HealthCare

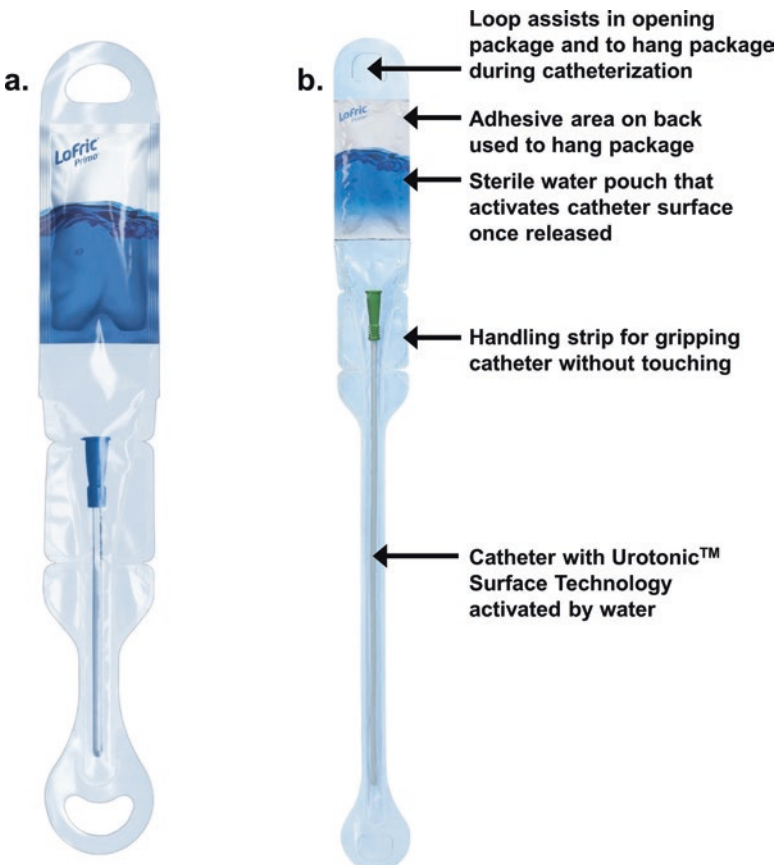


Fig. 2.21 HC catheter packaged with sterile water, once released, activates catheter coating. Ability to place close to patient with adhesive attachment. Available in sizes for men, women, and children, straight or Coudé tip. (LoFric® *Primo*™)—Courtesy of Wellspect HealthCare

reduction in hematuria, pain, and higher patient preference, for HC catheters. One study found no difference in the number of symptomatic UTIs versus noncoated catheters [10]. However, a study by the same group [44] found that the use of a HC catheter reduced the risk of UTI in the acute period and significantly delayed the time to first UTI for HC versus a plastic uncoated catheter. A systematic review of RCTs that compared HC catheters and PVC catheters was performed by Rognoni and Tarricone [45]. The authors conducted a separate data analysis to combine data on frequencies of UTIs and hematuria. The separate analyses took into account reused standard catheters. The results showed that HC catheters were associated with reduced risk of UTIs. These authors considered both single-use and single-use plus reused catheter scenarios. HC catheters with high osmolality (e.g., LoFric®) seemed to lower the risk of hematuria. HC catheters may also be useful for persons with urethral strictures or discomfort during catheterization [28].

HC catheter with lower osmolality however, have the disadvantages of varying surface drying times and some become "sticky" when dry. Also, the design of these catheters varies in terms of material, length, and flexibility, and there is no research comparing the different products.

Fig. 2.22 HC catheter 12/18 Fr with separate drainage bag for males or females—(*SpeediCath*® Compact Male with *SpeediBag*® (optional)—Courtesy of Coloplast Corp.

Special Features and Devices for IC

Assistive devices have specific features that may facilitate a patient in successful self-catheterization. They include mirrors, catheter holders, and devices to aid in meatal location (see Fig. 2.24). Some IC kits have features to facilitate IC by persons with impaired hand function (e.g., persons with quadriplegia). For example, some kits have loop holes or an adhesive tab to allow the kit to be hung on the wheelchair or on a wall (see Fig. 2.25), or to insert a thumb for easy opening (see Figs. 2.20b and 2.23a). A physician with tetraplegia developed a device to hold the penis in place during catheter-

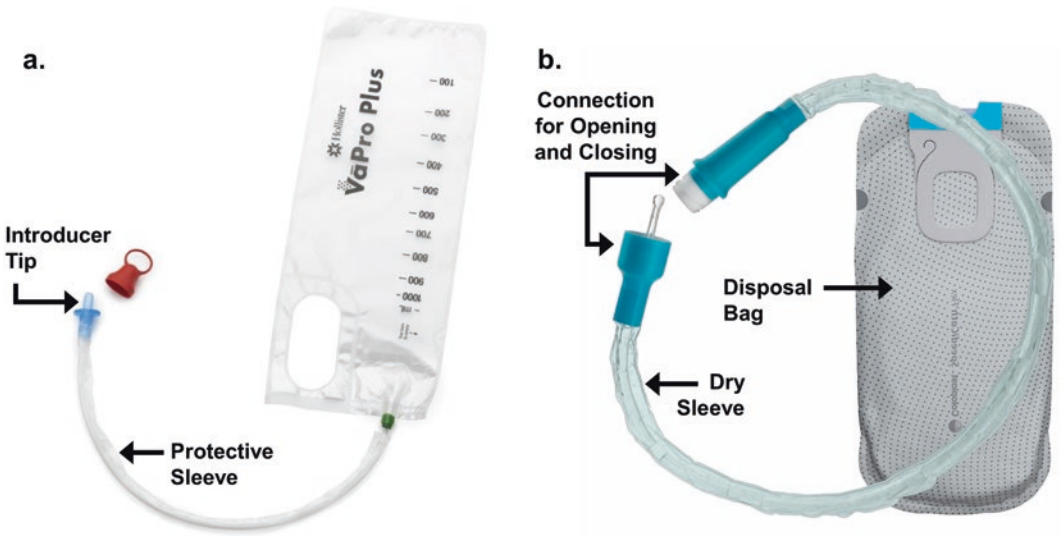


Fig. 2.23 Touch-free HC catheter with protective sleeve and protective tip to protect catheter from contamination. Protective sleeve is pulled back while catheter is inserted. Drainage bag attached. Comes in standard and pocket size. (**a**) Straight and Coudé tip available (*VaPro*™ *Plus)*—Courtesy of Hollister Inc. (**b**) Flexible tip that easily bends during insertion, water coats catheter and should be drained prior to insertion. (*SpeediCath*® Flex Coudé)—Courtesy of Coloplast Corp.

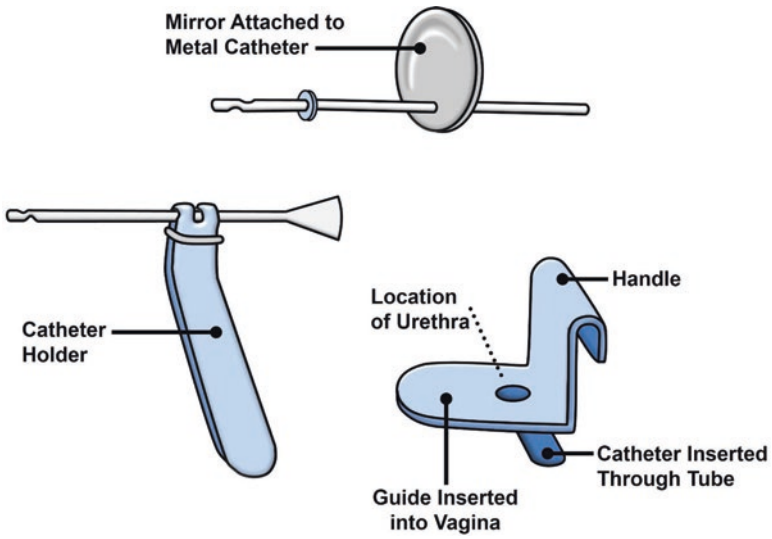


Fig. 2.24 Assistive devices for IC

Fig. 2.25 Adhesive on package allows catheter to be attached to wall for easy reach during catheterization

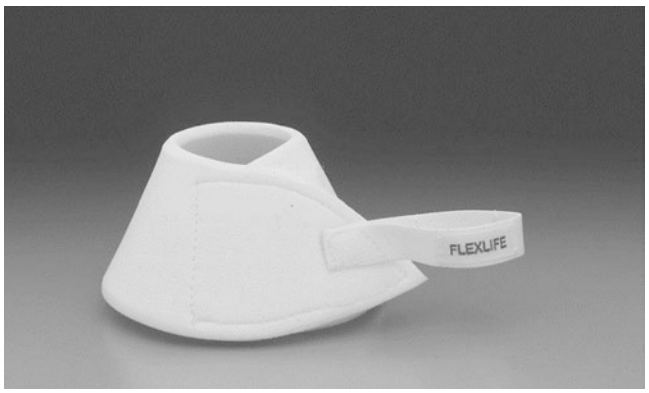


Fig. 2.26 Household Penis Collar—(www.icancath.com) holds penis in place, is reusable, and lasts approximately 2 years with daily use. It can be cleaned with soap and water [46]

ization (see Fig. 2.26 House Hold) [46]. The PerfICath (see Fig. 2.27) single-use catheter kit was also developed by the same physician. The sleeve is designed to be placed between the fingers and the catheter is advanced with the sleeve, not requiring the use of a finger grip. It is designed to allow the catheter to be pulled back into the sheath after use. It contains a gel reservoir, introducer tip, and two drainage ports for either fast or slow drainage. A hydrophilic version is being developed. Other catheter manufacturers have developed devices to facilitate gripping slippery HC catheters (see Fig. 2.28 U-Cuff Universal cuff or Fig. 2.29 LoFric® gripper tool) or other catheters. Devices exist that either hold the catheter steady for insertion (see Fig. 2.30) or spread the female labia to ease insertion (see Fig. 2.31).

Other IC kits have special features to facilitate advancing a catheter with use of gross, rather than fine grasp (see Fig. 2.32 Gripper catheter). Mike Ritmiller, a physician assistant who specializes in urology, developed a device that is designed to lie on the man's legs, to serve as a platform to hold and advance an IC closed system (see Fig. 2.33).

Urine Collection Devices/Urinals for Use With Intermittent Catheterization

Many persons who perform IC use external or "condom" catheters to collect urine in between catheterizations. These are discussed in Chap. 3. Persons who use individual catheters not in kits may empty their urine into a variety of receptacles, including typical hard plastic urinals. However,

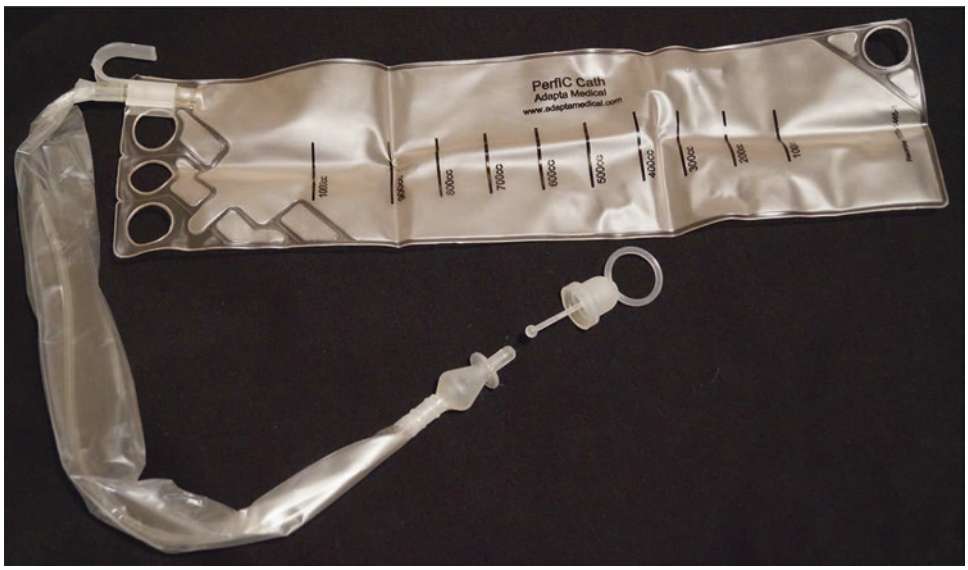


Fig. 2.27 PerfIC Cath (www.adaptamedical.com)

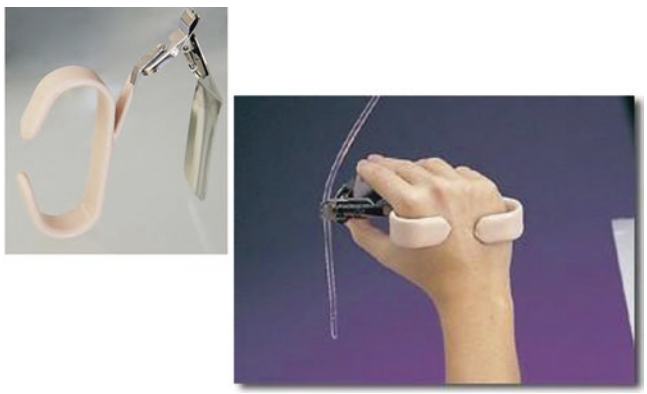


Fig. 2.28 U-Cuff—Universal cuff for limited hand function

these receptacles are often bulky and not well suited to carrying. The Uribag® (see Fig. 2.34 Uribag® 2 views) was designed for use by campers and is not marketed as a medical device. It consists of a flexible rubber bag attached to a hard plastic tube, with a cover that can be closed, allowing urine to be stored if necessary for later emptying in a suitable location. If the bag is pushed into the sleeve, it is compact and unobtrusive and looks like a large roll of camera film. Both male and female versions exist (see Chap. 7).

Promoting Patient Adherence To Intermittent Self-Catheterization

The health care provider and the patient must adhere to IC recommendations. Adherence to the prescribed IC frequency is important as it can directly impact the function of both the lower and upper urinary tracts, and may influence UTI risk [47]. According to Drake et al. [3], no guidelines or consensus exist on suitable intervals for bladder emptying. Ideally, catheterization frequency should be based on a diary (see Table 2.2), which records fluid intake, voided and catheterization volumes. If the patient is voiding and performing IC, recording and monitoring both volumes would assist with determining returning bladder function, and catheterization adherence. Additionally, PVR, and urodynamic parameters should be assessed, if available (detrusor pressure, bladder compliance) [16]. Inadequate catheterization frequency and elevated PVRs will lead to UTIs [16]. The largest catheterization volumes may occur in the morning, especially in older adults and those with edema. These persons should consider performing catheterization right before going to bed.

There are, however, barriers that patients face when self-catheterizing that may ultimately limit adherence. There are only a few studies examining adherence to IC [47]. Chai et al. [48] examined adherence rates to IC in SCI patients and reported that 71% were still using IC after a mean of 5.9 years. No studies were found that examined adherence in samples that included non-SCI individuals or that compared self-reported catheterization frequency to that prescribed by health care providers [49].

Both internal and external factors may pose as barriers to successful IC. Internal, patient-related factors include physical or psychological barriers. Physical barriers refer to the practical factors that hinder catheterization and psychological barriers refer to the psychosocial and cultural aspects that may restrict its use. External factors involve the quality of the IC teaching, supervision, follow-up, and catheter availability in the community.

In a study by Seth and colleagues [6], the most commonly reported barrier was lack of access to a public toilet (34%). Other barriers included difficulty positioning to insert the

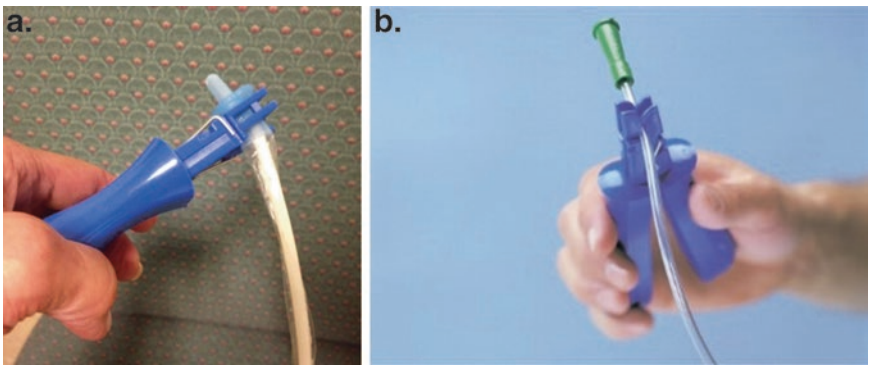


Fig. 2.29 (**a**) Catheter tool at catheter tip. (**b**) Catheter tool at catheter funnel end. (LoFric® *EZ-Grip Tool*)—Courtesy of Wellspect HealthCare

Fig. 2.30 P hold—Courtesy of Manfred Sauer

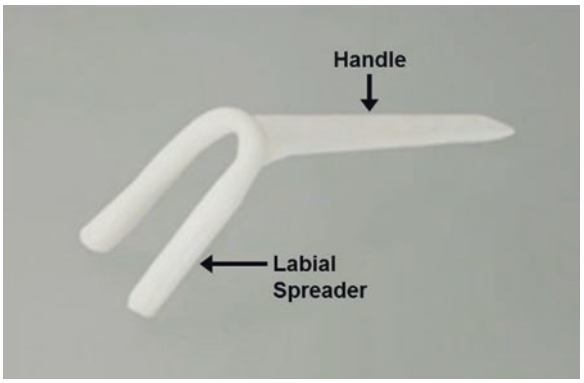


Fig. 2.31 Labial spreader—Courtesy of Manfred Sauer

Fig. 2.32 Gripper catheter—Courtesy of Coloplast Corp.

catheter (25%) and problems with dexterity (21%), especially in patients with multiple sclerosis (MS). Cost of supplies was also a barrier (18%). Only half of the patients claimed to be completely satisfied with IC, 40.9% were somewhat satisfied, and 9.1% were not satisfied [6].

Dexterity was reported as a common barrier to IC, due to spasticity, which often affects patients with neurological problems such as MS and those with SCI [49]. In a study by Zlatev et al. [50], 23.3% of patients with an SCI lacked upper extremity function to self-catheterize. Up to 50% of patients abandon use of IC within 5 years [51]. These authors suggested that IC 'dropout' may be due, in part, to a patient's physical inability to independently perform IC. To assess if hand dexterity or upper extremity strength are barriers, consider the use of a tool, such as the Pencil and Paper test described by Amarenco et al. [52]. This test employs a series of simple tasks using a pencil and paper that mimics the ability to open the packaging and handle a catheter, as well as the cognitive strategies required.

Anatomical barriers that can potentially reduce the success and ease of IC are obstructions to the outflow of urine from the bladder and are usually either due to an enlarged prostate or to urethral stricture disease [6]. In these cases, a Coudé tip or olive tip catheter should be recommended.

Relevant cognitive domains required to perform self-catheterization include comprehension, attention, memory, and motor planning, and therefore, the assessment of the patient should include a brief assessment of these domains. Motor

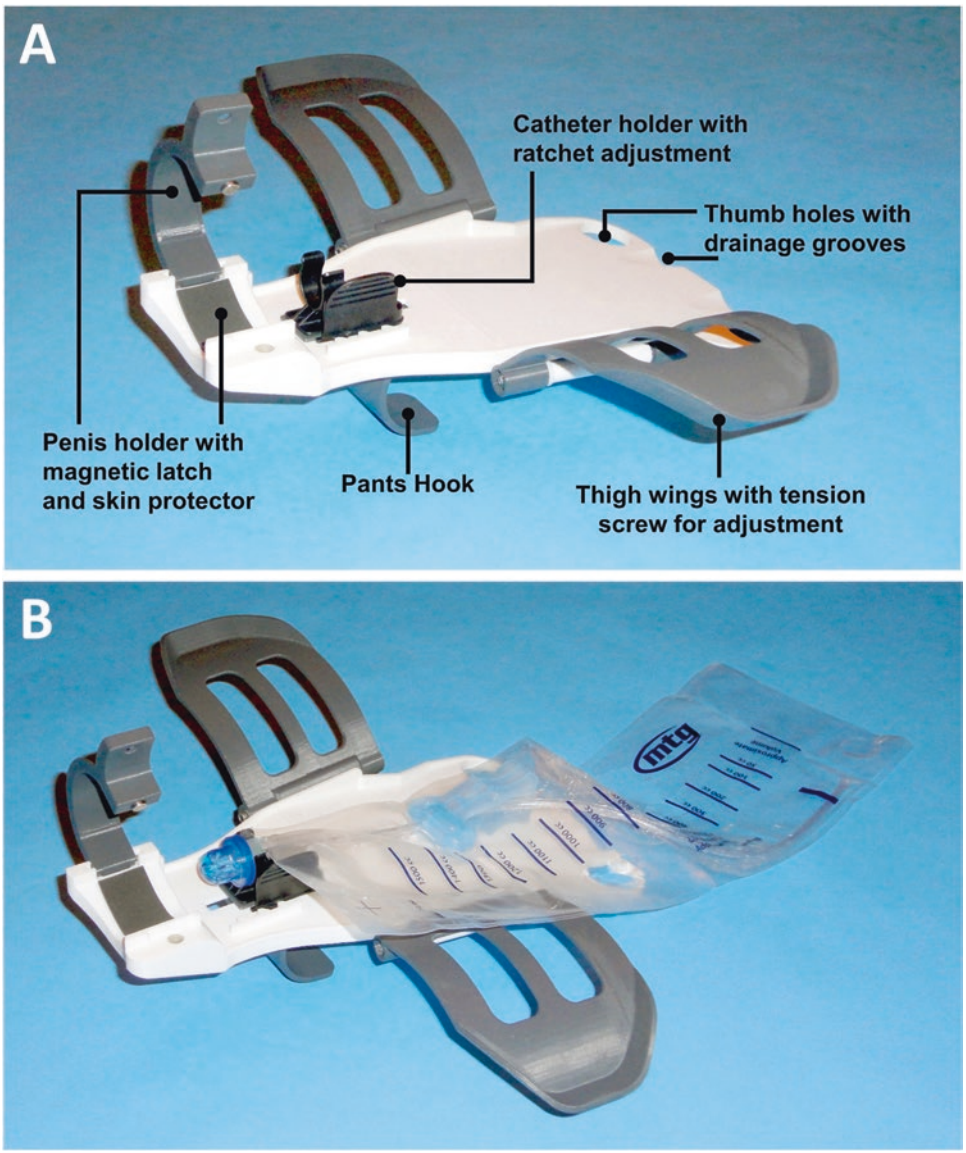


Fig. 2.33 Eagle board is a patented assistive device to allow patient with limited dexterity to self-catheterize. (**a**) Different components of Eagle board. (**b**) Eagle board with catheter in place—Courtesy of Medical Technology of Georgia (MTG)

Fig. 2.34 Uribag® – available in male and female sizes - Kinsman Enterprises, Inc. in the US

Table 2.2 Catheterization diary

Date	Time	Voided volume	Catheterization amount	Fluid intake	Comments
–	–	–	–	–	–
–	–	–	–	–	–
–	–	–	–	–	–
–	–	–	–	–	–

Record in ounces or millimeters the date, time, and amount you urinate (void) and/or catheterize and the amount of fluid intake

planning includes the ability to conceive, plan, and carry out a skilled, non-habitual *motor* act in the correct sequence from beginning to end. Incoming sensory stimuli must be correctly integrated in order to form the basis for appropriate, coordinated *motor* responses. For successful IC, the individual should be aware of the need to catheterize and respond

accordingly. Memory of the technique is also paramount, including the correct sequence of steps for the procedure, as well as measures to ensure hygiene. One study in both young and older adults found determinants of adherence related to lack of knowledge, complexity of the technique, misconceptions, –fears, shame, motivation, quality, and continuity of professional care. In younger persons, availability of materials, physical impairments and resistance to a sickness role could further reduce adherence [53]. Patient education should include exploring patient fears and misconceptions of the risks of IC. Patients also cite the inability to access the right type of catheter as a reason for discontinuing IC [54]. Catheter size, type, and material influence catheterization comfort. It is crucial, therefore, that the patient selects a catheter with which they are competent and comfortable using [6].

Many factors may affect patient adherence to successful IC. When patients are discharged home with IC, it is important to identify what barriers may affect their adherence. Patients need ongoing professional support to help ensure that they have access to the education, correct supplies, resources and followup.

Complications

IC is a common procedure, but is not without complications. Annual follow-up is needed to prevent and/or determine complications. A repeat bladder evaluation including renal (upper tract monitoring), bladder and/or urodynamic function has been recommended [3]. The following are the most common complications seen with IC. Their prevalence increases in long-term IC patients.

Urinary tract infection: Incidence of *asymptomatic* bacteriuria is as high as 60% in IC users, but patients may develop resistance to organisms if they are treated inappropriately with antibiotics. UTIs remain the most frequent type of infection in persons with SCI&D, with an average of 2.5 episodes per year [30]. Before World War II, urinary tract complications were considered to be the number one cause of death in the acute period after SCI. However, advances in urologic diagnosis and management through the use of urodynamic assessments and IC have reduced acute deaths and complications, improving the urinary tract–related quality of life for persons with SCI&D. Despite these advances, morbidity from UTIs remains common. In this regard, optimal urinary tract management is critical not only for the prevention of complications and illnesses, but also for the optimal social integration of the person with SCI&D.

There are certain populations who may be at greater risk for CAUTIs. Myelomeningocele patients may have NLUTD that predisposes them to UTIs, and such infections can have detrimental effects on their already compromised urinary tract. End-stage renal disease occurs in 15% of myelomeningocele patients and the mean age for transplantation in this patient population is 27 years. One of the first lines of management to guard against renal damage in selected patients is the implementation of IC. The choice of catheter (e.g., HC catheter) may decrease CAUTI risk in this population [55].

Frequency of IC, bladder overdisension, female gender, non-hydrophilic coated catheters, behavioral/hygiene factors, and poor education have all been found to increase the risk of a CAUTI [40, 56]. Table 2.3 lists possible causes of CAUTIs. A recent review reported low rates of complications or infections with IC when compared to IUC [13].

Urethral injury: Repeated catheterization has the potential to cause mechanical injury to the urethra, resulting in hematuria urethritis, cystitis, stricture, and other complications such as false passage [58]. To reduce urethral trauma, generous lubrication of the catheter is recommended. Prostatic irritation and prostatitis, epididymitis, and orchitis can occur in persons performing IC. Urethral strictures are seen more often in patients using latex catheters. This is felt to be related to cellular toxicity due to elutes from rubber causing urethral erosion over time, particularly in males [58]. These strictures can occur either in the anterior (meatus, penile-pendulous urethra, bulbar urethra) or in the posterior portion (membranous urethra and prostatic urethra) of the urethra.

Difficulty with catheter insertion can be a sign of the presence of a urethral stricture. It is felt that the higher the frequency of catheterization, the less the urethral changes. This might be due to the fact that those individuals regularly performing IC develop more skill in catheterization and therefore, have less chance of urethral trauma. False passage may be caused by infection and inflammation of periurethral tissue. De Ridder et al. [40] noted catheter-induced hematuria and leukocyturia secondary to repeated trauma, which contributed to the development of UTIs. They also reported a lower rate of UTIs among HC catheter users, but did not find a significant difference in pyuria, hematuria, or bacteriuria between the two groups. Sarica et al. [35] found decreased urethral trauma and microhematuria with either hydrophilic or gel lubricated coated catheters compared to PVC catheters. Other complications can occur. For example, upper urinary tract damage can occur if management is not optimized. Newman and Willson outlined potential complications related to IC in detail [1].

Scrotal complications: Epididymitis has been reported in 10–29% of patients who perform IC using PVC catheters [59] and in 6% of patients using low-friction HC catheters. This infection appears to be more common in men who develop a urethral stricture. Men may also experience prostatitis.

Bladder-related complications: Hematuria is frequently seen during the initiation of IC, but should not be a persisting problem. New-onset hematuria may indicate a UTI or stricture or a number of other conditions, including malignancy. Bladder stones caused by the introduction of pubic hair or loss of the catheter in the bladder, can occur in patients

Table 2.3 Causes of CAUTIs

Cause	Reason	Solution
Inadequate catheterization frequency	Can lead to bladder overdistension, increased intravesical pressure with long periods of urine stagnation increasing the risk of UTI	Catheterizing on a regular schedule will keep the bladder empty and eliminate urine stasis
Incomplete bladder emptying when catheterizing	Residual volume left in the bladder after catheterization provides environment for bacteria proliferation	To ensure adequate emptying, patients should perform a gentle Credé maneuver as the catheter is removed
Inadequate fluid intake	Companion problem to inadequate frequency of emptying. When low urine volumes are produced (<1200 mL of urine per day), patients are less inclined to empty at desired intervals, producing urine stagnation and bladder overdistention	Total daily fluid intake (from foods and all types of beverages) is approximately 2.7 L/day for women and 3.7 L/day for men Most adults adequately meet their daily hydration needs by letting "thirst be your guide"
Poor catheterization technique, and catheter care	Inadvertent introduction of bacteria into the bladder. Increased risk of urethral trauma	Consider re-evaluation of catheterization technique of the person performing catheterization Consider a HC catheter to prevent urethral trauma Consider using a catheter gripper to minimize contamination Consider use of a catheter with an introducer tip to prevent introduction of bacteria at the distal end of the urethra
Excessive fluid intake	If the person cannot or will not adjust fluid intake appropriately for the IC schedule, he/she risks periodic or regular bladder overdistention, and possible overflow UI Excessive intake could produce bladder volumes >500 mL at one time or would be evidenced by the need to catheterize more than 6 times a day	Encourage regular fluid intake, small amounts spaced hourly between breakfast and the evening meal and reducing to sips thereafter
Nocturnal polyuria	Some patients (e.g., those with SCI&D, MS and older adult patients) may have nocturnal polyuria related to inadequate antidiuretic hormone secretion at night or impaired cardiac condition	Large fluid intake in the evening (after 7 PM) should be discouraged Catheterize prior to bedtime and during the night as needed Consider a trial of desmopressin administration at bedtime with careful monitoring of serum sodium levels and cardiopulmonary fluid status or edema
Traumatic catheterization	Breaks in the bladder urothelium and urethral lining increase the risk of infection Difficulty passing the catheter may lead the person to avoid performing catheterization	Assessment of catheterization technique to help correct faulty insertion technique Consider an alternative catheter design (Coudé-tip, hydrophilic coated) to ease passage

Adapted from Newman and Wein [57]

performing long-term IC. There have been anecdotal reports of short-length catheters with a smooth, soft funnel end being inserted and "lost" in the bladder. The literature reports only a few cases of squamous cell cancer of the bladder in patients performing IC [60].

Risk Factors for Development of UTI in Persons on IC

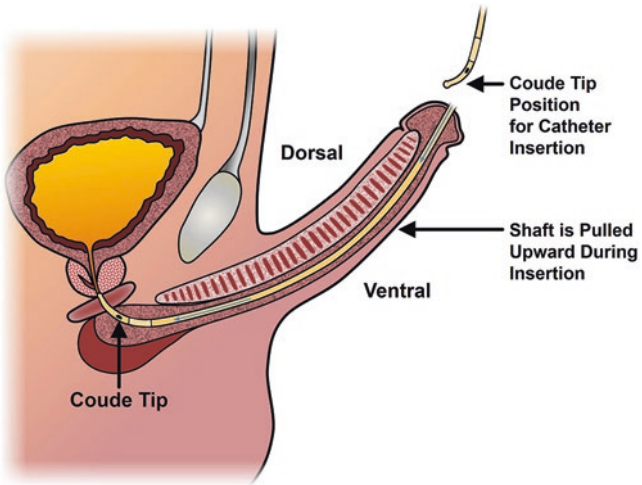
Causes of intermittent catheter-related UTIs, include inadequate frequency of emptying, inadequate emptying at the time of catheterization, inadequate fluid intake, poor catheterization technique, poor catheter care, excessive fluid intake or nocturnal polyuria (leading to bladder overdistension), and traumatic catheterization. Catheterizing less than 3 times per day and mean catheterization volumes over 400 ml are associated with occurrence of UTI [1].

Prevention of Catheter-Associated UTI (CAUTI)

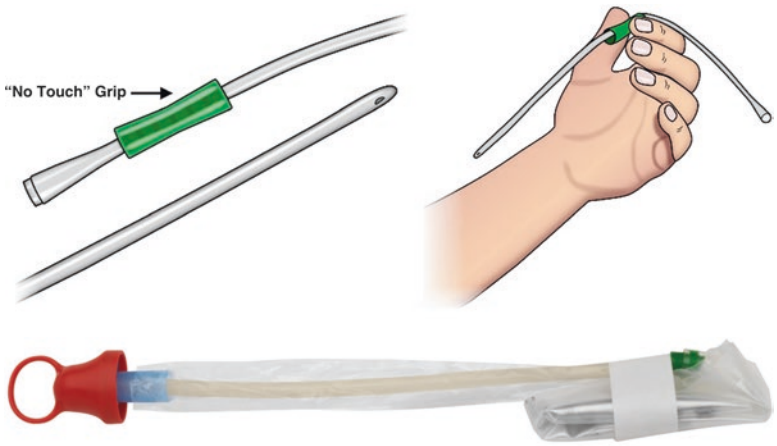
Table 2.4 provides a list of Best Practices for the Prevention of CAUTIs.

Table 2.4 Best practices for prevention of CAUTIs

1. Education and teaching are necessary to prevent any IC-related complications
2. Maintenance of hygiene, particularly of the hands and perineum
   - Hands should be thoroughly washed before attempting catheterization
   - The genitalia should be washed daily with soap and water and always cleansed from front to back
   - It is preferable to perform catheterization before a bowel program to minimize fecal bacteria contamination of the urethra
   - Immediate perineal hygiene is recommended after vaginal intercourse as the act of intercourse may push fecal bacteria into the urethra. Avoid spermicidal lubricants in sexually active females as these products may alter normal vaginal and lower urethral flora
3. Assist the female patient in identification of the urinary meatus and anatomical position of the vagina in relation to the meatus. The use of a mirror, placed so that the patient can visualize perineal structures can be very helpful
4. If postmenopausal female patient has hypoestrogenized perineal tissue, consider transvaginal estrogen medication
5. Teach male patients the correct positioning of the male urethra during insertion of the catheter to minimize trauma as the catheter passes through curved portions of the urethra



6. Instruct patient to be careful to avoid touching the tip of the catheter and/or letting it touch other surfaces. In patients with recurrent infections, consider the use of a "no-touch" catheter or "no-touch" grip or a catheter that has a protective sleeve through which catheter is inserted (e.g. *VaPro Plus*) a seen in the pictures to the right



Hydrophilic coated "no touch" catheter passed through a protected sleeve and drained into an integrated collection bag.

7. Use of a generous amount of lubricant along the length of the catheter (especially male patients) since dry catheters may cause excoriations in the urethra leading to an entry point for bacteria contamination
8. Keep bladder as empty as possible by having patients catheterize at least 4–6 times a day, approximately every 4–6 hour (h) or as often as needed to keep catheterized volume ≤500 mL. Keeping the bladder as empty as possible will prevent over-distension of the bladder and increases in intravesical pressure, all of which will preserve an adequate blood supply to the bladder wall
9. Encourage use of a new catheter each time performing IC. Most catheters are manufactured and packaged for single sterile use. Never reuse a hydrophilic coated catheter
10. If patient also has irritative bladder storage symptoms (e.g., urgency, frequency), consider prescribing an anticholinergic/antimuscarinic medication
11. Drink adequate amount of water so that urine is light yellow to yellow all day long. The color of urine can be a quick way to know if fluid intake is adequate (light) or inadequate (dark). If the color gets dark or urine has foul smell, increase water intake
12. Acidification of the bladder may prevent bacteria growth. In the non-catheterizing populations, cranberry capsules and juice have been shown and recommended to help prevent the growth of bowel bacteria in the urethra and the bladder
    - Cranberry ingestion may be contra-indicated in some patients (e.g., those prone to oxalate or uric acid calculi)
    - Cranberry is contraindicated in patients on anticoagulation therapy and should not be recommended to this group
13. Lactobacillus in the diet (yogurt) has been shown to prevent *E. coli* from growing in the urethra
14. Hiprex 1000 mg combined with Vitamin C 1000 mg capsules twice daily is thought to acidify urine enough to prevent bacterial growth in the bladder and is recommended in patients with recurrent UTIs

Adapted from Lamin and Newman [2], Newman and Willson [1], Newman and Wein [57], and Wilde et al. [61]

Management Strategies for Infection Prevention

Several mechanical strategies have been developed to prevent UTIs in individuals who use urinary catheters. These strategies include use of sterile technique, closed-system kits, coated catheters, and catheterization on a more frequent basis.

Ensuring adequate bladder emptying by frequency of catheterization may prevent UTI. Woodbury et al. [56] noted that patients who catheterize infrequently (once/day) were at greater risk of developing a UTI. This was probably related to higher volumes of urine in the bladder at the time of catheterization and longer dwell times of the bacteria in the bladder.

Fluid management for persons with NLUTD can be a challenge. Fluid restrictions of 2 liter per day (L/day) are often applied for persons using IC. In addition, individuals may need to restrict fluid intake before bedtime. Many individuals need to catheterize one or more times during the night, especially if a significant postural diuresis occurs. Dry mouth, which may occur with antimuscarinic medications routinely used to improve urine storage capacity, can further complicate fluid management. There are no prospective studies specifically evaluating optimal fluid intake in persons with SCI&D [28].

Medical strategies for the prevention of UTIs in individuals with SCI&D have been largely unsuccessful. Therefore, identification of novel agents that can successfully reduce rates of UTIs in individuals with SCI&D is an important clinical and research objective. The following sections review the evidence for UTI prevention when using these strategies.

Antibiotic prophylaxis: Antibiotics are not indicated unless signs or symptoms of illness are present. Signs of systemic illness or sepsis are obvious indications for treatment. Other signs, such as changes in the degree of spasticity, may or may not indicate a need for antimicrobial therapy. Furthermore, improvement of symptoms after antibiotic treatment does not necessarily correlate with permanent eradication of the infecting organism. Reid [62] reported persistence of antibody-labeled bacteria in the bladders of persons with SCI&D on antibiotic therapy. Use of antibiotic prophylaxis, which is often successful in individuals without neurogenic bladder dysfunction, is less effective in the population with SCI&D. This may be because of rapid recolonization and development of bacterial resistance. In addition, non-antibiotic-based medical therapies, including methenamine salts (mandelate or hippurate), have largely been unsuccessful.

Nonantibiotic Prophylaxis: A multitude of over-the-counter and prescription products exist for prevention or treatment of UTIs. Many of these products are poorly studied, studied in limited populations, or have been studied with mostly negative or conflicting results. The wide variety of agents attest to the scope of UTIs as a public health problem.

- *Cranberry*: Cranberry products have been shown to reduce the ability of bacteria to adhere to the urinary tract walls. The active components in cranberry, known as proanthocyanidins (PACs) , are large condensed tannin molecules with unusual A-type linkages exhibiting strong bacterial anti-adhesion activity [63]. Thus, PACs are thought to prevent bacterial adhesion to the bladder wall. Results with standard cranberry preparations have been mixed. In the largest study to date, Lee and colleagues [64] found no benefit of oral cranberry capsules, methenamine hippurate, or a combination in preventing UTIs. Hess et al. [65] reported UTI reductions in 47 male patients with SCI&D for any given month while on cranberry over a 6-month period. However, almost 75% of this group used external/condom catheters as their primary method of bladder drainage, making results difficult to interpret. Linsenmeyer et al. [66] in a 4-week study found no difference in bacteria or leukocyte counts for patients with SCI&D randomized to cranberry supplementation compared with a placebo.

  Jepson and Craig, in a Cochrane review published in 2012 [67], reported that "there is some evidence that cranberry juice may decrease the number of symptomatic UTIs over a 12-month period, particularly for women with recurrent UTIs. Its effectiveness for other groups was less certain. The large number of dropouts/withdrawals indicates that cranberry juice may not be acceptable as a long-term treatment option. However, properly designed studies with relevant outcomes are needed." The investigators concluded that cranberry products cannot be recommended for prevention of recurrent UTIs. More recently, a cranberry supplement with a higher concentration of the presumed active ingredient, proanthocyanidins, has shown efficacy in women [68]. Studies in SCI &D have not been completed, although more concentrated proanthocyanidins with standardized potency are available and being studied [28]. The in vitro effects of cranberry proanthocyanidins in preventing adhesion by P-fimbriated uropathogenic *Escherichia coli* are well described. Specifically, a dose response relationship has been established between proanthocyanidins and a decrease in bacterial virulence [69, 70]. However, only a few in vitro trials have examined the use of cranberry ingredients to reduce the recurrence of UTIs in patients in the general population over an extended period [68, 71, 72]. Comparisons are difficult to make because the supplements used and amount of proanthocyanidins present in commercially available preparations are not standardized [63].
- D-*Mannose*: Products containing D-mannose alone or in combination with cranberry based compounds (e.g., Cran-Actin [Solaray, Neutraceutical International Corp, Park City, UT]) are frequently used. Kranjcec and colleagues found a lower risk of recurrent UTIs in women taking D-mannose powder (15%) or nitrofurantoin (20%) versus no prophylaxis (60%) during a 6-month period [73, 74]. In addition, the D-mannose group had significantly fewer side

effects. The study excluded women with interstitial cystitis, diabetes, urinary tract anomalies, or those taking hormone therapy. We found no studies of D-mannose specifically in persons with SCI&D. Research with investigational mannosides (which is found in D-mannose) to prevent bacterial adherence is ongoing [75].

- *Methenamine*: Kevorkian et al. [76] found a lower occurrence of UTIs in a small group of persons with SCI&D taking methenamine plus urinary acidification with ammonium chloride, compared to no treatment. As mentioned earlier, Lee et al. [64] found no effect of methenamine alone. There are also a variety of prescription products containing methenamine mandelate or hippurate combined with methylene blue, salicylates, and urinary acidifiers (benzoic acid) or pH buffers (sodium phosphate). Whether these cocktail formulations have superior efficacy is unknown, because these agents are not well studied [28]. Recent CAUTI guidelines state that methenamine salts should not be used routinely for prevention, but when used, urinary pH should be maintained lower than 6.0 [25].

Bacterial interference: Darouiche and colleagues, in two separate prospective studies [77, 78], have found that persons whose bladders were colonized with *E. coli*, 83,972 were significantly less likely to develop a UTI during follow-up. Beereport and colleagues [68] performed a recent review and meta-analysis of randomized controlled trials of nonantibiotic prophylaxis for adults with recurrent UTIs. These investigators evaluated the efficacy, safety, and tolerability of available agents. Seventeen studies met the criteria for analysis. The oral immunostimulant OM-89 decreased the rate of UTI recurrence, with a good safety profile. However, there are no specific studies of this agent, derived from heat-killed *E. coli* serotypes, in persons with neurogenic bladder dysfunction. These investigators' meta-analysis also reported efficacy for cranberry in reducing UTI recurrence in two studies.

Coated catheters: Catheters coated with silver or antibiotics such as nitrofurazone have been developed to potentially reduce the frequency of CAUTIs. Most of these are indwelling/Foley type catheters. An intermittent hydrophilic single-use catheter coated with nitrofurazone was available but has been taken off the market. An in vitro study of *E. coli* and *E. faecalis* found that silver impregnation had little effect on bacterial adherence and nitrofurazone had a significant effect for only the first 5 days [79]. Intermittent catheterization would present a different challenge, as the catheter is only in contact with the urethra for a brief period of time.

Other studies involved indwelling coated catheters, rather than those for IC. A large multicenter trial [80] evaluating short-term use of antimicrobial catheters in hospitalized adults found no evidence supporting their routine use. Neither silver-coated nor nitrofurazone-coated catheters produced clinically significant reductions in CAUTI in a randomized trial of hospitalized adults. Numerous others have assessed silver-coated or nitrofurazone-coated catheters, some finding short-term reductions in bacteriuria or CAUTI [81]. However, long-term evidence is lacking.

A systematic review by Shamout and colleagues [8] found that although results reported in the literature are inconsistent, single-use HC catheters have an estimated UTI incidence between 40 and 60%, compared with 70–80% UTI prevalence in observational studies of multiple-use catheters.

Bladder irrigation is not recommended, but may be commonly performed by persons with SCI&D who use chronic IUCs for long-term bladder management. In addition, bladder irrigation with antimicrobial agents, such as neomycin or gentamicin is sometimes used for persons on IC. A temporary reduction in bacteriuria can occur, which may result in the growth of yeast. Antiseptics such as oxychlorosene at varying concentrations have been used for treatment of CAUTIs [82, 83]. However, current guidelines do not recommend routine bladder irrigation, because no evidence shows it reduces CAUTIs [25] and the practice of irrigation may itself increase the risk of a CAUTI. No difference in effectiveness at reducing bacteriuria has been found between saline and other irrigants (acetic acid, polymyxin/neomycin), including antibiotic solutions, in persons with IUCs [84]. In general, irrigation solutions are not believed to be effective in eliminating bacteriuria [85].

Techniques/Procedures for Intermittent Catheterization

Sterile and nonsterile techniques may be used with catheter insertion. Some hospitals support the use of nonsterile technique and specific bladder training programs, but most facilities support the use of sterile technique in restricted areas and in certain patient populations, such as the immunosuppressed [33].

Intermittent self-catheterization can be performed in the supine, sitting, and/or standing positions. The location for performing ISC depends on the patient's daily routine. The most popular location for men performing ISC is the bathroom/restroom, using the toilet to drain the urine (see Fig. 2.35) whereas many women prefer sitting on a chair (see Fig. 2.36). The Patient Education Tools found at the end of this chapter depict varying positions and places for performing ISC for both male and female patients.

Most importantly, the catheter must be inserted in a clean and atraumatic way. The requirements include cleaning hands with soap and water prior to catheter insertion, using a clean catheter and lubricant, if needed, and cleansing the urethra meatal area. Use of water versus antiseptic for periurethral cleansing prior to catheterization did not increase the risk for UTI [86, 87] or bacteriuria [88]. Atraumatic insertion requires a proper catheter size, sufficient lubricant,

Fig. 2.35 Male self-catheterizing

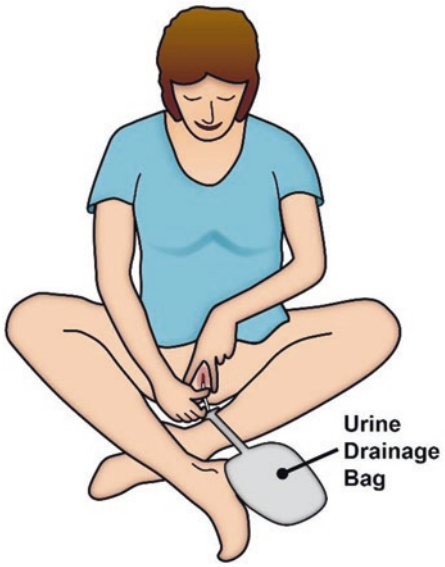


Fig. 2.36 Female self-catheterizing with a drainage bag attached to the catheter

gentle insertion through the urethra, and in men, correct position of the penis so catheter passes smoothly through curved portions of the urethra (see Fig. 2.37).

During the rehabilitation phase, sterile IC can be taught to patients with adequate hand function. When patients are discharged home, they are transitioned from sterile IC to intermittent self-catheterization.

Patient-Related Questionnaires

Questionnaires have been developed to assess patient satisfaction with IC. These may assess parameters such as the type of catheter or kit, ease of use, privacy or discreetness, ease of transport or storage, and other quality of life measures. The Intermittent Catheterization Satisfaction Questionnaire (InCaSaQ) has been found to be reliable, valid, and have good patient comprehension and acceptance [89]. The same group developed the Intermittent Catheterization Difficulty Questionnaire (ICDQ), which was found to be a valid test for evaluating catheter use and patients' difficulties during ISC [90]. The Intermittent Self-Catheterization Questionnaire (ISC-Q) was also demonstrated to be a valid and reliable measure of aspects of ISC-related quality of life [91, 92]. It is questionable whether these questionnaires have been used in clinical practice.

Educating the Patient about Intermittent Catheterization

According to Newman and Willson [1], nursing practice lacks uniformity and standardization in teaching a patient how to catheterize since most nurses base their teaching on learned experience. Initially, many patients have reservations and may be extremely reluctant to perform any procedure that involves the genitalia, but this is basically a "fear of the unknown." Self-catheterization is a technical procedure and the patient must learn how to hold and handle the catheter, how to identify the urinary meatus, and how to care for the catheter. In women, in addition to the assistive devices previously reviewed, the use of a mirror, used at the time of the initial teaching, can assist the woman in identifying the meatus and surrounding structures (e.g., vaginal opening, clitoris). Lapides et al. [9] found that women may initially use a mirror, but after several days can locate the urethral meatus by palpation and stop using the mirror. There are many devices that incorporate a mirror for perineal visualization, which are shown in Figs. 2.38 and 2.39. The devices shown in Fig. 2.39 are "thigh-spreaders" that are helpful in women who have abductor spasms or are unable to separate their thighs. Women may facilitate self-catheterization by placing a tampon or having a finger on the opposite hand in the vagina to isolate the location of the meatus or using a device shown in Fig. 2.40 that is anchored in the vagina and held against the meatus with holes to insert the catheter. Patients and/or caregivers should demonstrate understanding of, and ability to perform catheterization under the supportive supervision of a nurse.

Patient Information

- *Intermittent Catheterization for Men Patient Education Tool.*
- *Intermittent Catheterization for Women Patient Education Tool.*

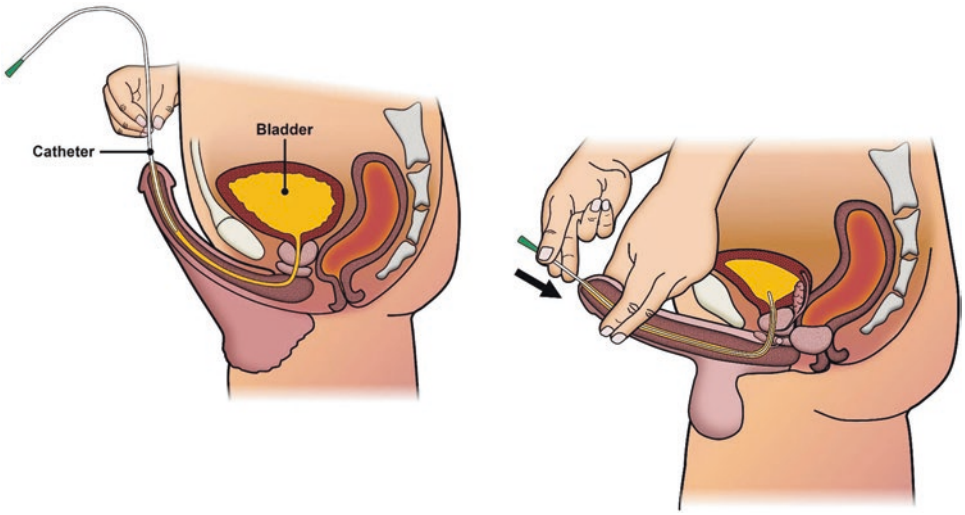


Fig. 2.37 Correct position of the male urethra for atraumatic catheter insertion—Courtesy of Diane Newman

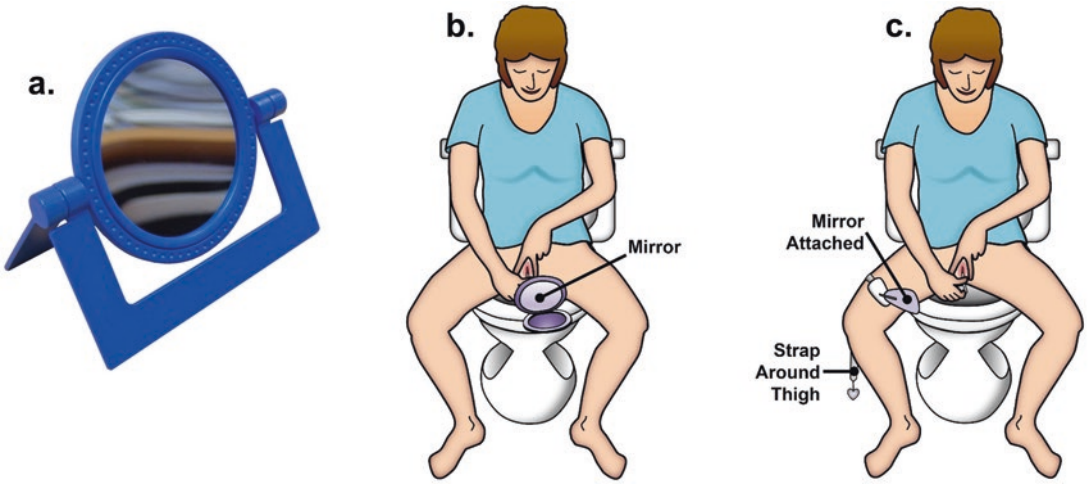


Fig. 2.38 (**a**) Mirror for visualization of perineum—Courtesy of Wellspect HealthCare. (**b**) Woman catheterizing using a mirror—Courtesy of Wellspect HealthCare. (**c**) Woman catheterizing using a leg strap mirror—Courtesy of Wellspect HealthCare

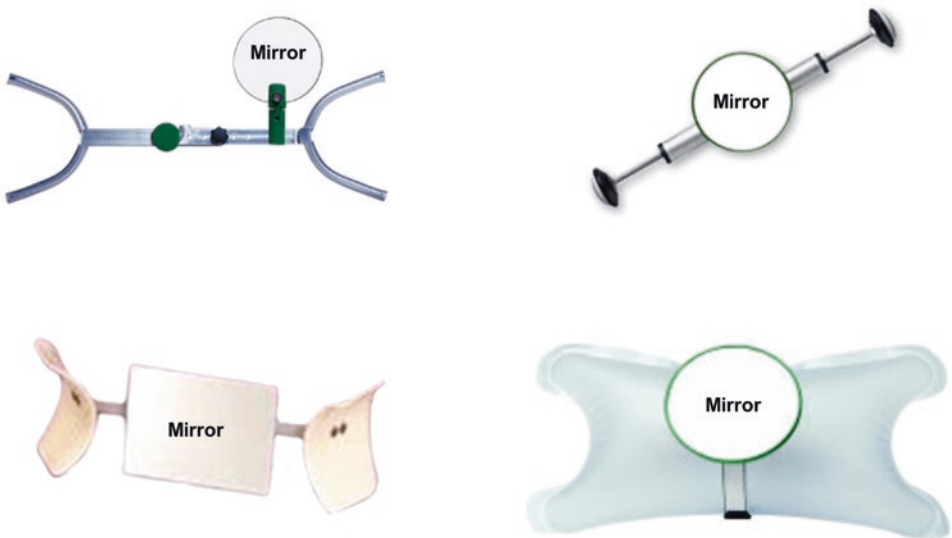


Fig. 2.39 Leg spreaders with mirrors for women, end of device is positioned against upper thigh to keep them separated, mirror is positioned so the perineum can be visualized

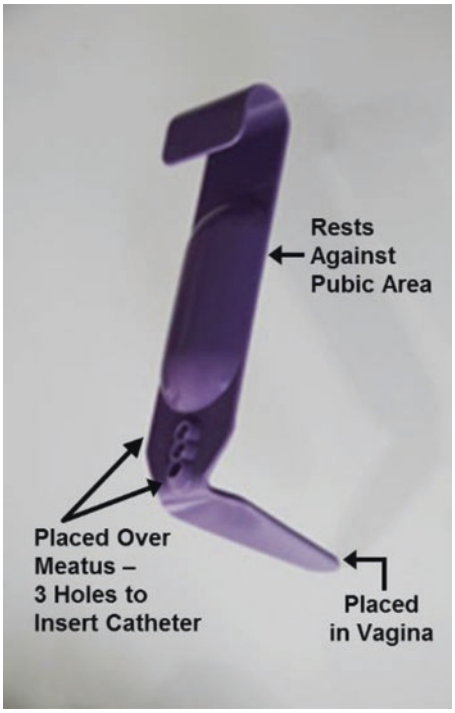


Fig. 2.40 Female device to aid in meatal location. Asta-Cath Female Catheter Guide - A+ Products, Inc.

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Intermittent-Catheterization for Men Patient Education Tool

What Is Intermittent Catheterization?

Intermittent catheterization, called IC, is when you put a tube called a "catheter" into the urethra (which carries urine from your bladder to the outside) and pass it into your bladder to drain urine. Once all the urine is drained, the catheter is removed. Your bladder may need to be drained several times a day. Catheters can be made from rubber, latex, silicone or polyvinyl (PVC) material. A catheter used for intermittent bladder drainage is coated with a lubricant (gel) or a liquid, so that it can be passed easily in your bladder and avoid hurting the urethra. Some are coated with a slippery water solution called "hydrophilic." Others have no lubricant in the package or on the catheter so you will need to add it. Some are covered in a protective sleeve, so that the catheter is not directly touched. Others require that you break a water packet found in the package that will coat the catheter. All are "single-use" catheters, so they are only used once. Most catheters are about 16 in. long and have a straight or curved tip.

Why Do I Have to Catheterize?

If you cannot empty your bladder completely (called urinating or voiding), you may have certain medical problems. After prostate surgery, you may need to catheterize for a short period of time. People with neurologic (nerve problems) of the bladder may need to catheterize for a longer time. You may need to catheterize your bladder several times a day.

What Can Happen if I Do Not Catheterize?

If your bladder is unable to empty, it can cause a number of problems. It can overstretch, causing permanent damage to the bladder muscle and even kidney damage. If urine is left in the bladder for long periods of time, you can develop a bladder infection. Not being able to urinate can also cause pain, urine leakage, bladder urgency, frequent urination, and awakening many times at night to urinate.

What Is the Procedure I Should Follow?

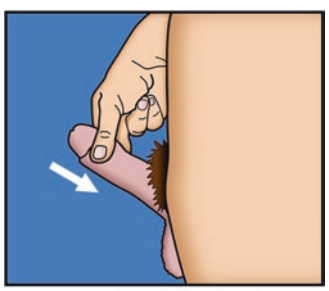
Gather your supplies close to you before you start, so that you can easily reach them. Read the instructions on the catheter package so you know how to use that specific catheter or if you need to prepare the catheter (like needing to coat the catheter with lubricant).

There are several different positions you can try for the catheterization as seen in the pictures on the right. Find one that is most comfortable and works for you. Arrange your clothing so that it does not get in your way.

Wash your hands with soap and water or use a bactericidal soap. Never skip a catheterization because you cannot wash your hands. It is more important to empty your bladder.

If this is the first catheterization of the day, wash the top of your penis, wiping around the opening at the head of the penis with soap and water.

As seen in this picture, with your non-dominant hand (the one you do not use to write with), hold your penis firmly and directly under the head. Then lift up and straighten your penis. Keeping the penis up straight will allow the catheter to pass easily.

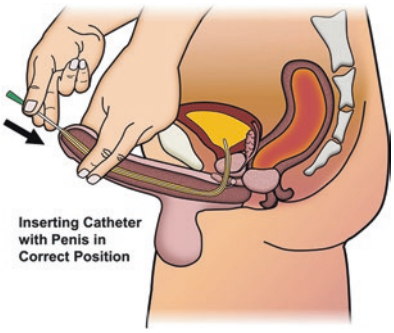


Correct Way To Hold Penis

If you are right-handed, hold the catheter in your right hand 2–3 in. from the tip. The smooth end of the catheter has small holes—this is the end that goes into your bladder, so try not to touch this end. Pass the catheter slowly into the opening of the urethra.

Some resistance may be felt halfway. If this happens, stop and take a few deep breaths, then continue to pass the catheter, gently, but firmly. Do not force the catheter by pushing down on the penis. Push the catheter in 1–2 in. more after urine starts to flow out. Urine may not always flow out. Let the urine drain until it stops. Pushing down on the bladder may help the bladder empty completely.

Hold the catheter tip up as you pull it from your penis so that urine does not spill. You can also pinch the catheter to prevent urine from spilling on your clothes.



How Often Do You Have To Catheterize

You should catheterize *at least* 4 times a day, about every 6 h and at bedtime. Do not let your bladder hold more than 13 oz (around 400 mL) of urine. This is very important as larger amounts may cause problems, like bladder infections.

If your catheterized urine volume is more than 13 ounces (or around 400 mLs), then catheterize yourself more often. Record the amount you urinate and the amount of urine drained from the catheterization.

Taking Care of Your Catheter

These are "single use" catheters, which means you can only use them once so throw the catheter away after you use it. You will use a new catheter each time.

Helpful Tips

- Never force the catheter into your urethra. If you meet resistance and cannot pass the catheter, stop, take a few slow deep breaths, which will cause the urethra to relax allowing the catheter to slide in.
- Control the amount you drink by only drinking between **six** and **eight**—8-oz drinks or a total of 48–64 oz of liquids each day unless you are on a fluid restriction.
- If catheterizing while traveling or working, consider using a pocket or closed catheter system.
- It is important that your bowel movements are regular as this will make it easier for you to empty your bladder completely,
- If you find that you awaken from sleep during the night and feel the need to catheterize, try to not drink after 7:00 pm. This may help you sleep through the night without needing catheterization

What Problems Might Occur?

- *Bleeding when you catheterize*: There may be a little amount of bleeding when you insert the catheter as it may have irritated your urethra. It should stop but if it does not, call your doctor or nurse.
- *Infection*: Symptoms of an infection include fever, chills, shivering, back pain, blood in your urine, not feeling well, and pain when passing the catheter. You may get one or two bladder infections a year, especially when you first start to catheterize. But, you should not get an infection as long as you wash your hands, and the area around the opening to the urethra is clean. Reusing the same catheter more than once can lead to a bladder infection, so always catheterize with a new catheter.

The Following Catheter Has Been Prescribed for You

□ Clear Plastic (PVC) □ Red Rubber (Latex) □ Hydrophilic Catheter □ Coudé-Curved tip

□ Closed catheter system/kit □ Catheter With a Protective Sleeve

Size_____ Length _____ Manufacturer_____

Intermittent-Catheterization for Women Patient Education Tool

What Is Catheterization?

Intermittent catheterization, called IC, is when you put a tube called a "catheter" into the urethra (which carries urine from your bladder to the outside) and pass it into your bladder to drain urine. Once all the urine is drained, the catheter is removed. Your bladder may need to be drained several times a day. Catheters can be made from rubber, latex, silicone or polyvinyl (PVC) material. A catheter used for intermittent bladder drainage is coated with a lubricant (gel) or a liquid, so that it can be passed easily in your bladder and avoid hurting the urethra. Some are coated with a slippery water solution called "hydrophilic." Others have no lubricant in the package or on the catheter so you will need to add it. Some are covered in a protective sleeve, so that the catheter is not directly touched. Others require that you break a water packet found in the package that will coat the catheter. All are "single-use" catheters, so they are only used once. Most catheters are about 6-12 in. long and have a straight tip.

Why Do I Have to Catheterize?

If you cannot empty your bladder completely (called urinating or voiding), you may have certain medical problems. After surgery, you may need to catheterize for a short period of time. People with neurologic (nerve problems) of the bladder may need to catheterize for a longer time. You may need to catheterize your bladder several times a day.

What Can Happen if I Do Not Catheterize?

If your bladder is unable to empty, it can cause a number of problems. It can overstretch, causing permanent damage to the bladder muscle and even kidney damage. If urine is left in the bladder for long periods of time, you can develop a bladder infection. Not being able to urinate can also cause pain, urine leakage, bladder urgency, frequent urination, and awakening many times at night to urinate.

What Is the Procedure I Should Follow?

Gather your supplies close to you before you start, so that you can easily reach them. Read the instructions on the catheter package so you know how to use that specific catheter or if you need to prepare the catheter (like needing to coat the catheter with lubricant).

There are several different positions you can try for the catheterization as seen in the pictures below. Find one that is most comfortable and works for you.

You can sit far back on the toilet or commode with legs spread, stand facing the toilet with one foot on the toilet seat or stand over the toilet. You can also lay on the bed with your legs spread and drain the urine in a container. Arrange or remove your clothing so that it does not get in your way when catheterizing.

Wash your hands with soap and water or use bactericidal soap but never skip a catheterization because you cannot wash your hands. It is more important to empty your bladder.

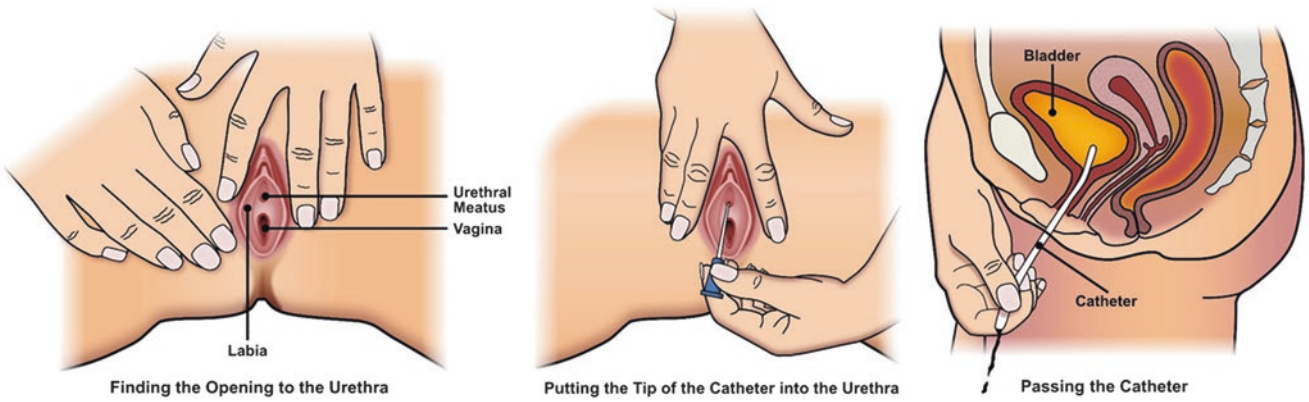
If this is the first catheterization of the day, wash the area around the opening to your urethra with soap and water.

As seen in the first picture below, use your non-dominant hand (the one you do not write with) to separate your labia with your 1st and 3rd fingers and identify your clitoris, urethra (urinary meatus) and opening to your vagina. If necessary, use a mirror to help find these parts.

Rest you non-dominant hand there. With your dominant hand, hold the catheter like a pencil, about 1–2 in. from the catheter tip.

One end of the catheter is smooth with small holes—this is the end that goes into your bladder, so try not to touch that end. Put this end in the urethra (the opening which is found directly above the opening to your vagina and below the clitoris), as shown in the 2nd picture.

When putting in the catheter, point the tip up. When the urine starts to flow, put the catheter in another 1 in. Let the urine drain until it stops. Push with your hand on your stomach to completely empty your bladder. Wait till urine stops draining, then slowly remove the catheter so any urine in the base of the bladder drains out.



How Often Do You Have to Catheterize?

You should catheterize *at least* 4 times a day, about every 6 h and right before you go to bed. Do not let your bladder hold more than 13 oz (around 400 mL) of urine. This is very important as larger amounts may cause problems like bladder infections because the bladder becomes too full of urine.

If your catheterized urine volume is more than 13 ounces or (around 400 mL), then catheterize yourself more often. Record the amount you urinate and the amount of urine drained.

Taking Care of Your Catheter

These are "single use" catheters which means you can only use them once so throw the catheter away after you use it. You will use a new catheter each time.

Helpful Tips

- Never force the catheter into your urethra. If you meet resistance and cannot pass the catheter, stop and, take a few slow deep breaths, which will cause the urethra to relax allowing the catheter to slide in.
- Only drink between **six** and **eight**—8-oz drinks or a total of 48–64 oz of liquids each day unless you are on a fluid restriction.
- If catheterizing while traveling or working, consider using a pocket or closed catheter system.
- It is important that your bowel movements are regular as this will make it easier for you to empty your bladder completely.
- If you find that you awaken from sleep during the night and feel the need to catheterize, try to not drink after 7:00 pm. This may help you sleep through the night without needing catheterization.
- If any questions or problems occur, call your doctor or nurse, especially if you are having trouble doing the catheterization or think you may have a bladder infection.

What Problems Might Occur?

- *Bleeding when you catheterize*: There may be a little amount of bleeding when you insert the catheter since it may have irritated your urethra. It should stop, but if it does not, call your doctor or nurse.
- *Infection:* Symptoms of an infection include fever, chills, shivering, back pain, blood in your urine, not feeling well, and pain when passing the catheter. You may get one or two bladder infections a year, especially when you first start to catheterize. But, you should not get an infection as long as you wash your hands and the area around the opening to the urethra is clean. Reusing the same catheter more than once can lead to a bladder infection, so always catheterize with a new catheter.

The Following Catheter Has Been Prescribed for You

□ Clear Plastic (PVC) □ Red Rubber (Latex) □ Hydrophilic Catheter □ Coudé-Curved and/or Olive Tip

□ Closed catheter system/kit □ With a Protective Sleeve

Size_____ Length _____ Manufacturer_____

External Catheter Collection Systems

3

Diane K. Newman and Alan J. Wein

Definition

External catheter collection systems (ECCSs) are devices that are attached externally to the pubic area and external genitalia [1]. They are connected to either a bodyworn product (e.g., pouch, pant, brief, strap) or a disposable bag to collect urine. An ECCS is not an actual urinary catheter because it is not inserted into the kidney, bladder, or urethra [2]. There are many more external product options available for men than women because the penis provides a natural extension onto which or over which other devices may be fitted [3]. For this chapter, ECCSs are categorized as follows:

- In men:
  - Soft, flexible condom-type catheters with internal or external fixation that fits over the penile shaft (male external catheter [MEC]) or a nonsheath, glans-adherent device or an inflatable external catheter. These are similar to a condom used for contraception, except that MECs are open at the distal end (tip), allowing urine to drain into a bag (see Fig. 3.1). Most are single-use disposable products.
  - ECCSs that contain a receptacle or cup for penis placement, tubing and a drainage bag. They may be either a single unit (receptacle and drainage bag as one piece) or a two-piece device. They differ from a MEC in that the device is secured firmly against the pubic area using a belt, strap, or cloth pants. They may be referred to as a "pubic-pressure catheter" or "bodyworn urinal" (see Fig. 3.2). Most are designed to be used over extended periods as they can be washed and reused multiple times.
- In men and women:
  - An ostomy-like pouch attached to the pubic area (external pouch [EP]) (see Fig. 3.3). An EP is similar to an ostomy bag in that the opening needs to be measured and cut to fit.

External catheter collection systems for men are also referred to as external catheters (EC), condom catheters, "Texas" catheters, urisheaths, or penile or urinary sheaths. These external systems are connected to some type of drainage bag, small or large, or a collection receptacle that may be fastened either around the thigh or lower leg or held in a sleeve or brief. The most common disadvantage with ECCSs is the failure to stay in place due to an individual's anatomy, incorrect sizing, or placement [4]. But not all ECCS perform the same, not one size fits all, and not all are suitable for all patients [5]. Knowledge about the various ECCS and their fitting can eliminate many of the difficulties attributed to them. Determining which ECCS is most appropriate for an individual patient requires careful user selection. Important performance characteristics include security (ability to keep a leak-proof seal and drain urine into a bag without leakage) and ease of application and removal of the catheter or pouch.

Indications

ECCSs are noninvasive devices that collect urine in men and women who experience moderate to severe urinary incontinence (UI). Table 3.1 reviews appropriate and inappropriate uses of an ECCS. They may also be used for men with lower urinary tract symptoms of urinary urgency and frequency in circumstances in which it would be difficult to make frequent trips to restrooms [5, 6]. It is not uncommon for older adult men, who may or may not be incontinent, to use a toilet during the day but wear an ECCS during the night when asleep. In women, external pouches are most

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D.K. Newman et al., *Clinical Application of Urologic Catheters, Devices and Products*, DOI 10.1007/978-3-319-14821-2_3

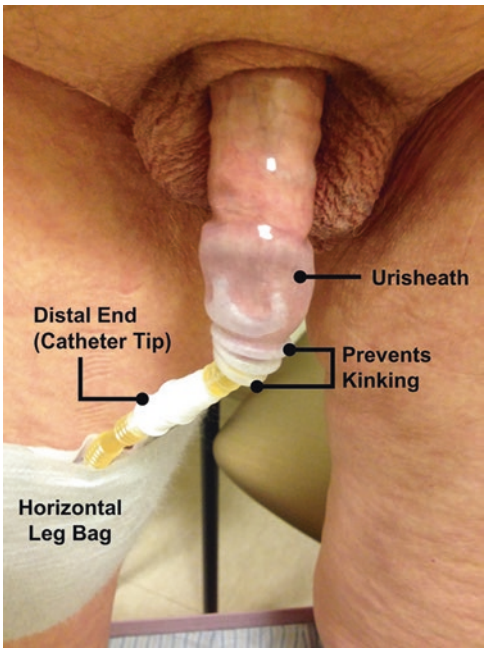


Fig. 3.1 Disposable male external catheter with leg bag—Courtesy of Diane Newman

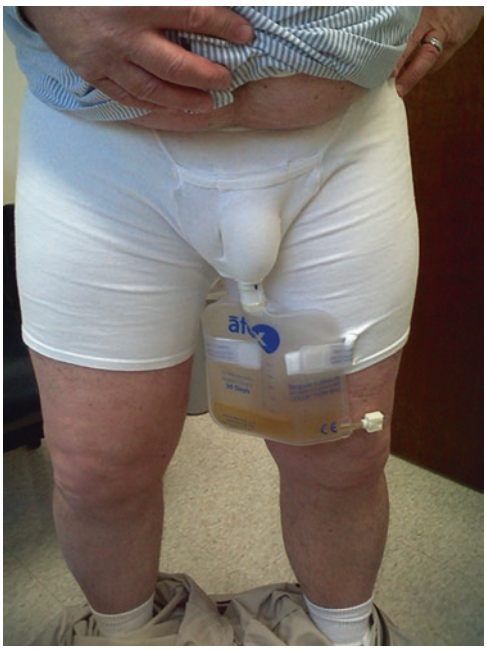
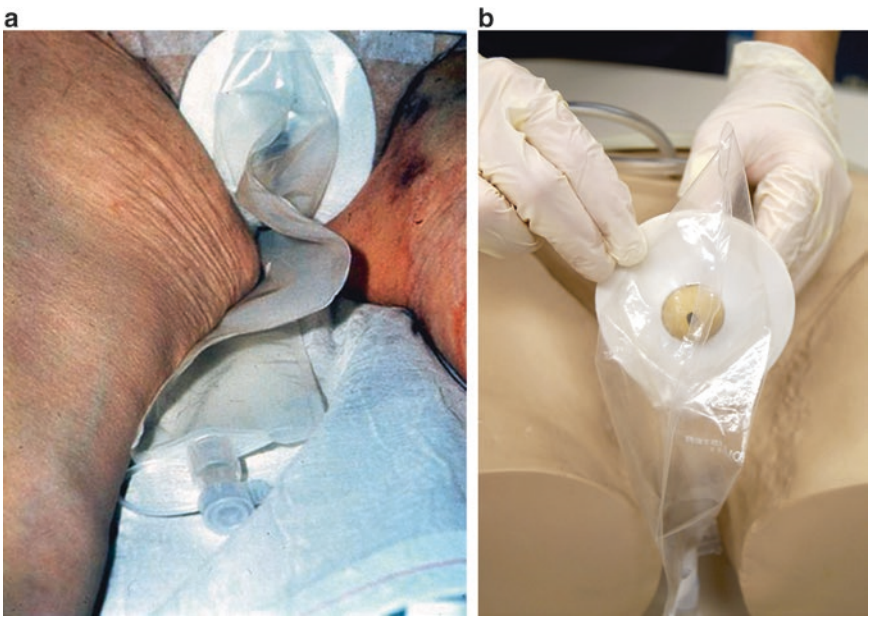


Fig. 3.2 Reusable bodyworn pubic pressure external catheter containment system AFEX—Courtesy of Arcus Medical

Fig. 3.3 External urinary pouch (**a**) Female (**b**) Male—Courtesy of Hollister Inc.



effectively used in those women with UI who are immobile. In men, an EP is indicated for men with UI who have a retracted and/or shorter length penile shaft or those who cannot use a disposable or reusable MEC.

The 2009 Centers for Disease Control and Prevention (CDC) Guidelines recommend that clinicians should "consider using external catheters as an alternative to an indwelling urinary catheter (IUC) in cooperative male patients without urine retention or bladder outlet obstruction" (p. 38) [7]. These recommendations are supported by other guidelines from medical and nursing professional organizations [8–11]. Cottenden et al. [12] recommended that external urisheaths, rather than an IUC, should be the urinary collection device of choice. When comparing an ECCS to an IUC, the advantages include no urethral instrumentation, no chance of urethral stricture, less incidence of bacteriuria, and less pain. Gray

Table 3.1 Appropriate and inappropriate uses of an ECCS

Appropriate use

- Male or female patients who experience UI without retention
  - Long-term care residents in nursing homes
  - Urinary containment for men with neurogenic bladder dysfunction and UI who have perineal sensation
  - UI (no skin issues) and difficulty turning due to excess weight from obesity or edema
- Patient request for external catheter to manage UI
- Post-prostatectomy male patient with significant postoperative UI who is returning to work or wants to return to activities (e.g., golfing)
- Daily (not hourly) measurement of urine volume that is required to provide treatment and cannot be assessed by other volume and urine collection strategies (e.g., acute renal failure work-up, bolus diuretics, fluid management in respiratory failure)
- Single 24-h or random nonsterile urine sample for diagnostic test that cannot be obtained by other urine collection strategies
- Reduction in acute, severe pain with movement when other urinary management strategies are difficult (e.g., turning patient to remove an absorbent pad causes pain)
- Managing overactive bladder symptoms and improving comfort in palliative care patients
- External catheter placement to reduce risk for falls by minimizing the need to get up to urinate

Inappropriate use

- Any type of urinary retention (acute or chronic, with or without bladder outlet obstruction)
- Any use in an uncooperative patient expected to frequently manipulate the ECCS because of such behavior issues as delirium and dementia
- Hourly measurement of urine volume required to provide treatment
- UI in patients with intact skin when nurses can turn/provide skin care with available resources when the patient has not requested the external catheter
- Patient or family request in a patient who is continent when there are alternatives for urine containment (e.g., commode, urinal, or bedpan)
- A need for a sterile urine sample for diagnostic test
- In a patient who does not have perineal sensation

Adapted from [1, 56, 57]

et al. [1] provide recommendations for improving use of ECCSs as part of a CAUTI reduction program.

Despite these recommendations, ECCSs are underutilized by clinicians. Nurses are not routinely taught about them during training, often believe that all urisheaths leak and/or fall off, and many find them difficult to fit. Many nurses and purchasers of MECs believe that "one size fits all." For men, there are many different types of ECCSs to choose from and it is worth trying different types of urisheaths and fixation methods to find the most appropriate one.

Prevalence

Determining the prevalence of ECCS use is difficult, as it varies widely amongst countries, cultural differences and insurance reimbursement. Conflicting results from the few available studies have left the role of ECCSs in hospitalized patients or long-term care (LTC) residents unclear [13]. Hebel and Warren [14] reported on the use of urine collection devices in 4239 residents of 53 randomly selected nursing homes in Maryland. They found that 10% of women and 15% of men were using such devices. Among bedfast patients, 47% of women and 58% of men were using a collection device. Those with pressure injury, 37% of women and 33% of men were using a urine collection device. Not surprising, most women were only using an IUC, whereas men were using a urethral IUC (43%), external (39%) or suprapubic IUC (15%).

Rogers et al. [15] assessed the use of urinary collection devices (external, intermittent, and indwelling catheters; pads or briefs) and examined predictors of IUC usage in skilled nursing facilities (SNFs). This retrospective cohort study was conducted in SNFs located in five states. Participants included residents who were admitted to SNFs in 2003 and who remained there for 1 year ($N = 557{,}302$). The predominant catheter type was an IUC with few residents (< 1%) using intermittent or external catheterization. Of the 57,302 residents, 7242 (12.6%) were using an IUC upon admission, which declined to 4.5% at 1 year ($P < 0.001$).

Most research available has been on men in Veterans Administration Medical Centers (VAMC) who report that an EC is more comfortable, less painful, and less restrictive on their activities than other devices (e.g., IUC) [16]. This study also indicated that nurses also preferred ECs to IUCs.

Description of Disposable Male External Catheters

Historically, MECs have been described as ineffective external urine collection devices. However, changes in the design, material, and type of MECs available have proven this description false. Edlich et al. [17] identified five desirable attributes for an MEC: (1) structural configuration that conforms to the anatomical configuration of the penis, (2) self-adhesive, integral to the inner surface for secure bonding, (3) transparency permitting a skin injury to be visible, (4) ability to elongate and retract during erectile function, and (5) avoidance of local or systemic allergic reactions.

The most popular ECCSs are those that are disposable (e.g., MECs) and changed every 24 hours (h) per manufacturer recommendations. The sheath is secured to the penile shaft by one of four methods: (1) a water-tight adhesive that is integral to the internal surface of the sheath, (2) a single- or double-sided adhesive strip that wraps around the penis with the sheath rolled over the strip, (3) a urisheath inflated with air once it is in place, or (4) a non-adhesive sheath that is kept in place with a Velcro™ strap [18, 19]. In all four methods, the sheath is applied by rolling it over the penis and urine drainage is accomplished by attaching the distal end (near the bag connector) of the sheath to a urinary drainage bag (leg bag or overnight bag) (see Fig. 3.4). Most MECs have a non-kinking and/or non-twisting junction between the catheter tip and drainage bag to reduce kinking/twisting at the distal end.

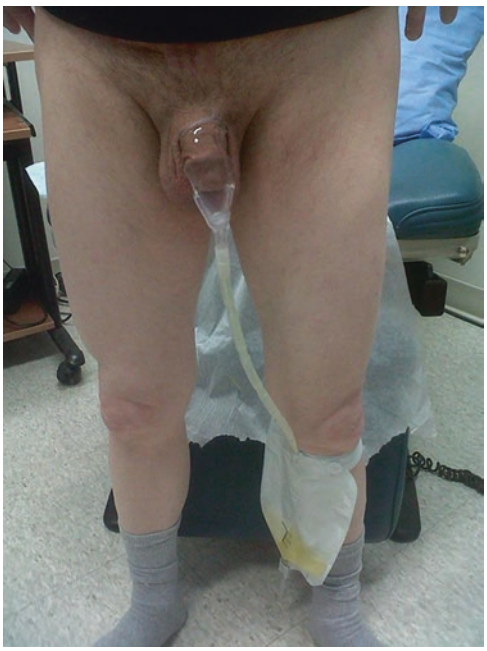


Fig. 3.4 Silicone MEC attached to leg bag—Courtesy of Diane Newman

Penile sheaths are not suitable for all men; in particular, they are not suitable for men who have a penis which is permanently retracted or for those men whose penis retracts when they sit or bend down. The sheath will roil off the penis as it retracts into the body, resulting in the sheath coming off and allowing leakage to occur.

Material

Both disposable and reusable types of ECCSs are made from a variety of material including latex rubber, polyvinyl (PVC), silicone, or synthetic polymers. Latex is used in many urologic products, including all types of ECCSs, because it is a soft and flexible material. But the presence of latex material in many catheters, devices, and products creates a greater risk of an allergic reaction in urologic patients. In general, the use of latex in the healthcare setting is being phased out. Silicone sheaths have the advantage that they are latex-free and transparent, allowing visualization of the penile skin. Silicone MECs are also skin-friendly because of their biocompatibility, as they allow the skin to breathe by permitting the transfer of water vapor and oxygen and reducing the amount of moisture build-up under the sheath. PVC is a synthetic and resistant material that contains plasticizers. Placticizers can be a problem in long-term users [2]. MECs also often use polyurethane (PU), a thinner material which may be more comfortable for the wearer.

Types

Self-adhesive or one-piece MECs are the most popular as they have an internal fixation of integral adhesive (adherent to the inside of the sheath) that sticks to the penile shaft [20]. They are rolled over the shaft of the penis (see Fig. 3.5) and pressed to ensure adherence. A section between the adhesive and distal end prevents kinking and the tip attaches to a drainage tube with a bag. Variations exist in the different types of adhesives, the placement of

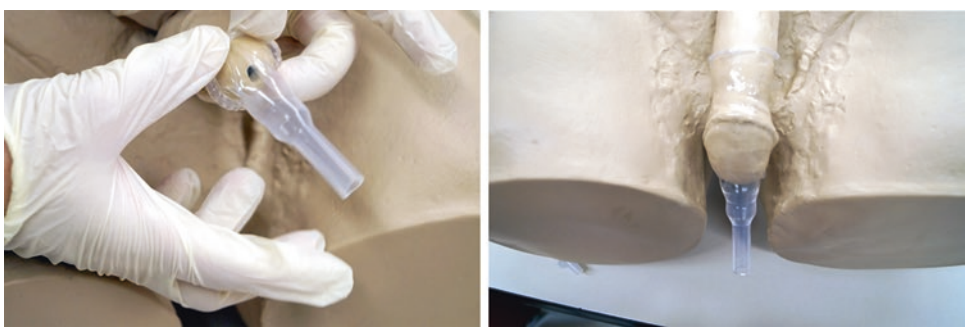


Fig. 3.5 MEC application (2 pics)—Courtesy of Diane Newman

the adhesive on the MEC, and the size of adhesive area [2] (see Fig. 3.6). Self-adhesives MECs are preferred because they are easy to self-apply, are more secure, and are covered by most insurers. All-silicone MECs cause less irritation and fewer adverse reactions and thus are recommended for men with a latex allergy [17] (see Fig. 3.7). Some adhesive MECs have an applicator or a strip (see Fig. 3.8) that may assist the individual or caregiver in unrolling the sheath. These catheters may also be useful for patients with reduced manual dexterity. To ensure adequate drainage, most have an "anti-kinking" outlet and/or "anti-twisting" internal flap feature that reduces kinking and twisting at the distal end of the MEC, near the connection to the drainage tube [12] (see Fig. 3.9).

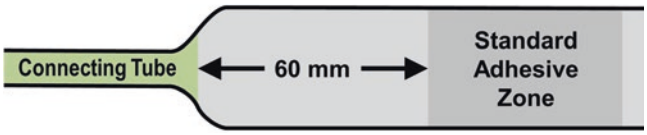


Fig. 3.6 Self-adhesive MEC (one-piece system) consists of three parts: the connecting tube, buffer zone, and adhesive zone. The size of the three parts differs between products and manufacturers

Fig. 3.7 Thin silicone soft breathable conforming MEC (Spirit) with 3 sizes: Style 1: sheath length 3 in., adhesive length 1.75 in. Style 2: sheath length 1.5 in., adhesive length 1.75 in. Style 3: sheath length 3 in., adhesive length 3 in.—Courtesy of C.R. Bard, Inc.

Two-piece sheaths have either an internal or external fixation method. External fixation methods are less effective than internal methods, as no adhesive is physically attaching the sheath to the penis, making the fixation less secure. Adhesive tapes are not recommended as they are inflexible and not designed for sheath fixation. They can result in constriction of the penis, interfere with voiding and cause trauma.

An internal fixation MEC has a double-sided hydrocolloid adhesive strip, separate from the sheath that has adhesive on both sides, and can be applied internally in a spiral fashion around the penile circumference (see Fig. 3.10). The thickness and size of adhesive strips can vary. The strip is wrapped around the circumference of the penis and the catheter sheath is then rolled up and over the penis and strip. Pressure should be applied to ensure adherence. A strip can be too tight around the shaft so men who use this type of MEC should have penile sensation and understand correct application. These double-sided strips are more elastic, do not tend to absorb urine, and are better able to accommodate changes in penile size. Such strips may be more appropriate for men who have erectile function.

A second type of two-piece sheath has an external fixation that is foam or a Velcro™ reusable strap (see Fig. 3.11) which is secured around the shaft of the penis once the

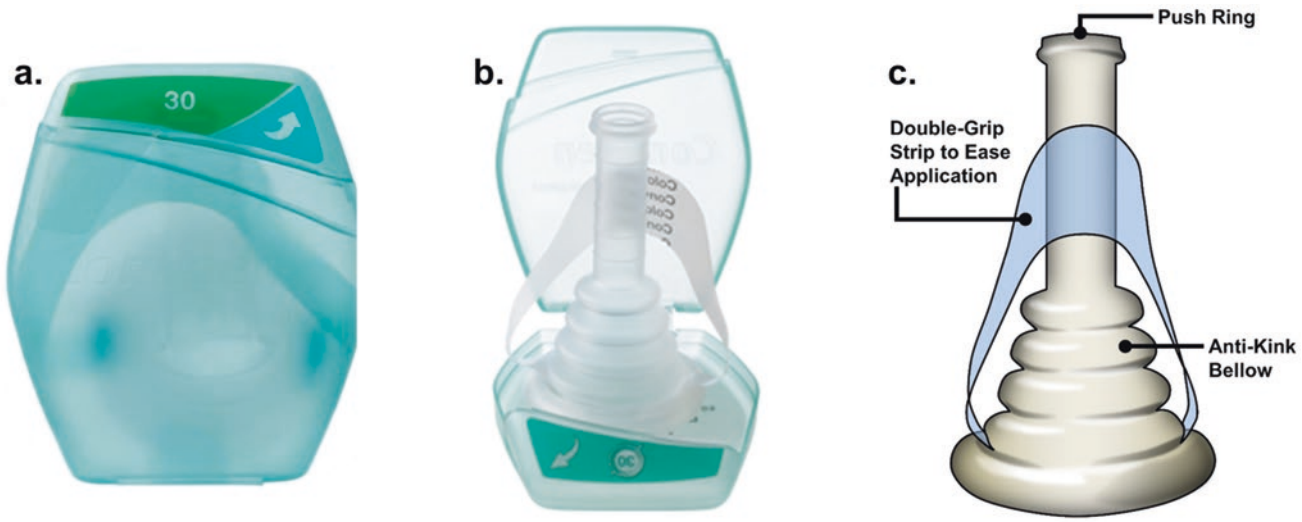


Fig. 3.8 (**a**) Conveen® *Compact Optima* MEC. (**b**) *Compact Optima* silicone MEC with applicator/pull-tab for easy application. (**c**) The loop of the double-grip strip can be pulled which may make MEC application MEC easier. MEC has a push ring at distal end (tip) of the MEC for secure connection to a leg bag and an anti-kink bellow to prevent backflow of urine—Courtesy of Coloplast Corp.

Fig. 3.9 Latex MEC with an anti-reflux valve and double convolutions that resist kinking and twisting and prevents urine backflow and leakage. *Extended Wear Male External Catheter*—Courtesy of Hollister Inc.

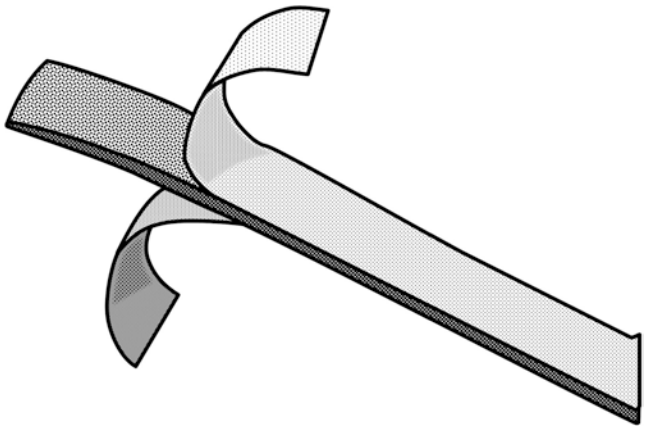


Fig. 3.10 Double-sided adhesive strip

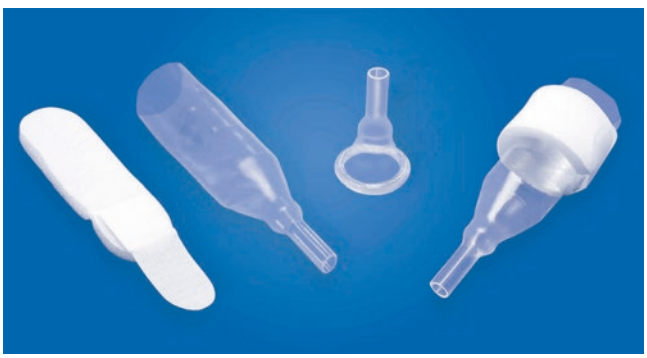


Fig. 3.11 Silicone MEC with Velcro™ or Foam external band—Courtesy of C.R. Bard, Inc.

nonadhesive sheath is applied. External fixatives are sometimes placed on the end of the MEC for extra security (especially when using a one-piece system). But foam straps are not elastic, so they will not stretch and should be used with caution [21].

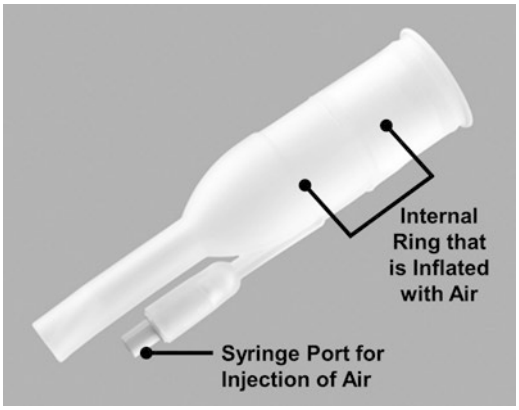


Fig. 3.12 Non-adhesive balloon-inflating MEC. The inflatable retention ring secures the catheter and can be easily deflated for removal. The retention ring must be positioned behind the head of the penis. It is non-sterile, reusable, and intended for single patient use only. (X-Large 33 m, Large 33 mm, Medium, 28 mm, Small 23 mm)—Courtesy of Cook Medical

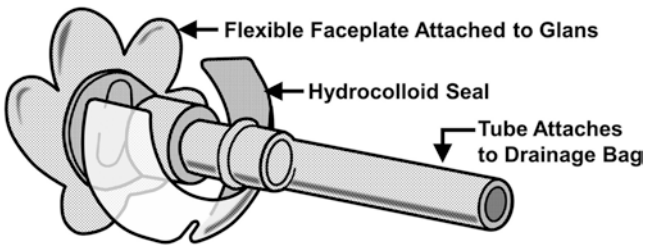


Fig. 3.13 Parts of the Reliafit or Mens Liberty External Male Catheter

A third type is an inflatable retention ring that secures the catheter (see Fig. 3.12) with air inflation, and is deflated for removal. The inflatable MEC is nonsterile and can be reused.

Some men prefer external fixation, especially in cases where the catheter is removed and replaced frequently. Catheters with a circumferential band may be too restrictive for the shaft of the penis and should be used only by men who are cognitively intact and have penile sensation because they are associated with an increased risk of penile strangulation. In addition, external, two-piece MCEs can be difficult to apply and may not be as effective as one-piece MECs.

Non-penile sheath, glans-adherent external device, a more recent device in the MEC category, is gaining in popularity. This device is a small, soft adhesive faceplate or wafer in the shape of a daisy flower that adheres to a small area of the glans penis around the meatus. A hydrocolloid seal (hypoallergenic, latex-free) is placed over the faceplate (see Fig. 3.13). Hydrocolloid polymer is the material often used to produce wound dressings. It has a central urine outlet opening to make a complete parameatal seal and directs all urine into a leg (see Fig. 3.14) or bedside collection bag [22]. This device functions like an ostomy device for normal male anatomy, directing all urine immediately away from the

meatus to establish an environment where the skin (including penile shaft and glans) is consistently protected from moisture or exposure to urine. By keeping the skin dry, the device prevents skin maceration, breakdown, and wounds. It is highly effective for all normal male anatomy. It allows the foreskin to return to a natural, forward position making it equally suitable for both circumcised and uncircumcised anatomy. If present, the foreskin must be pulled back to place this device and then returned to the natural forward position over the seal (see Fig. 3.15). The device is also a good urine containment product for men with a retracted penile shaft, who are obese with large girths, who experience frequent erections. Because this device is applied exclusively to the glans penis, it is recommended for patients with penile shaft ulceration, inflammation, irritation or for men who have developed an penile shaft allergic reaction to a more occlusive urisheath [23].

Preliminary data indicates that the occlusive nature of the parameatal seal and application site cleansing may reduce the incidence of infection to less than 4%, more than a 10-fold improvement over any other modality [24]. Parameatal glans hygiene is required prior to application, thereby reducing ambient bacteria. The parameatal hydrocolloid seal establishes an occlusive dressing that can prevent bacteria from accessing the urinary meatus. The hydrocolloid seal will adhere to clean, dry skin for an average of 24–72 h. Although initial applications may have a shorter wear time, the device may be worn up to 3 days. The seal turns a milky-white color when the device is ready to be changed. Soaking the seal with warm water will allow the device to slide off easily.

Proper application is essential for successful utilization of the device (see Fig. 3.16) and it requires more dexterity than in applying a one-piece sheath. If application is not per-

Fig. 3.14 *Non-penile sheath, glans-adherent* external device attached to drainage bag, the Reliafit or Mens Liberty External Male Catheter—Courtesy of BioDerm

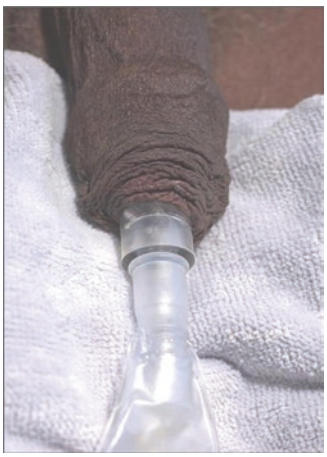


Fig. 3.15 Foreskin returned in place. When the foreskin is brought forwards, prepuce covers the faceplate and seal and only the outlet channel is visible. Reliafit or Mens Liberty External Male Catheter—Courtesy of BioDerm

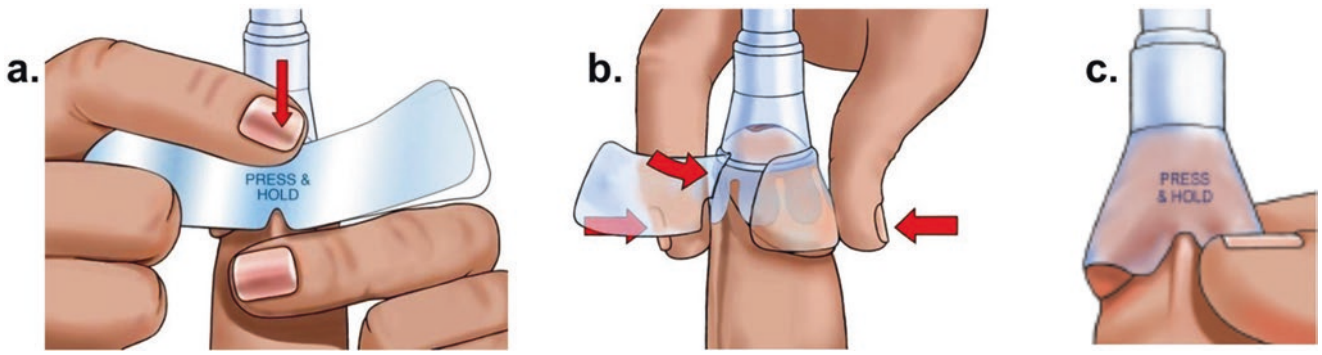


Fig. 3.16 Application of the Reliafit/Liberty Pouch. (**a**) A flexible "faceplate" is positioned by aligning the central hole over the external urethral meatus, pressed down over the glans penis avoiding wrinkles, and held firmly for 20 s. The end of the faceplate directs the flow of urine into a tube for collection in a bag. (**b**) Hydrocolloid seal is wrapped around the faceplate to ensure adherence. (**c**) Apply pressure for 20 s. A new Reliafit/Liberty Pouch, when applied to the glans penis, is translucent. As it absorbs water and other discharge from the skin, it gradually becomes opaque—Courtesy of BioDerm

formed correctly, the device may be more likely to come off early or leak. Patients who experience a sudden, large diuresis have reported a feeling of suction on the tip of the penis, which tends to be more noticeable than in patients who experience this sensation when wearing a more traditional form of MEC.

This device has two sizes: standard size is indicated in patients who have normal anatomy of the external urethral meatus. Men who have a hypospadiac or enlarged urinary meatus (e.g., spinal cord injury patients as a result of long-term use of IUCs), may need to use the XLS model which has a larger outlet channel. Patients should use the tube holder recommended by the manufacturer or a conventional thigh strap to secure the urinary drainage tubing to the leg to avoid undue traction. An extension tube may be necessary.

Descriptions of Disposable External Pouches

External pouches that resemble ostomy pouches are available for both men and women. These are one-time use devices and usually only stay in place for 24 h as the weight of the urine will pull the product off.

Material

There are currently only two available EPs and they are made from flexible vinyl.

Types

External pouches are modeled on ostomy appliances. One type is a bodyworn pubic pressure type flange, which fits over the penis and sits against the abdomen using straps (see Fig. 3.17). A second type is a pouch with a pectin-based adhesive skin barrier that secures the device to the pubis [25]. The pouch holds about 90 mL but is more effective if connected to a drainage bag (see Chap. 4) using an extension tube. The pouch can be left in place for up to 3 days.

In men, the opening of an EP may be widened to allow for application over the penis and the integral adhesive barrier is attached to the pubis (see Fig. 3.18). In women, the opening can also be widened, and the adhesive is placed over the mons pubis (see Fig. 3.19).

Pouches are available for men with a retracted penis or with a shorter length penis or who cannot use a regular MEC [26]. They are also available for nonambulatory incontinent women [27].

Prior to application, the skin should be cleansed and pubic hair removed at the base of the penis in men and the perineum in women. The hair should be trimmed, not shaved, because shaving causes more irritation. Pouches can be attached to dependent drainage.

In men, the base of the penile shaft is assessed. The opening in the adhesive surface of the hydrocolloid wafer barrier should be cut to the circumference of the widest point of the penis. The wafer opening should be large enough that the penis is able to pass through the pouch and be able to move freely

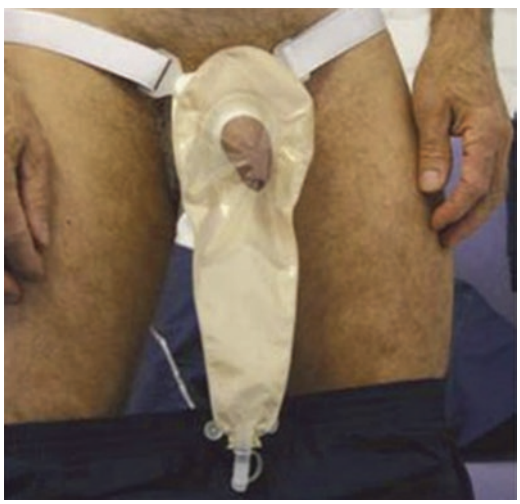


Fig. 3.17 Bodyworn pubic pouch with waist strap or belt

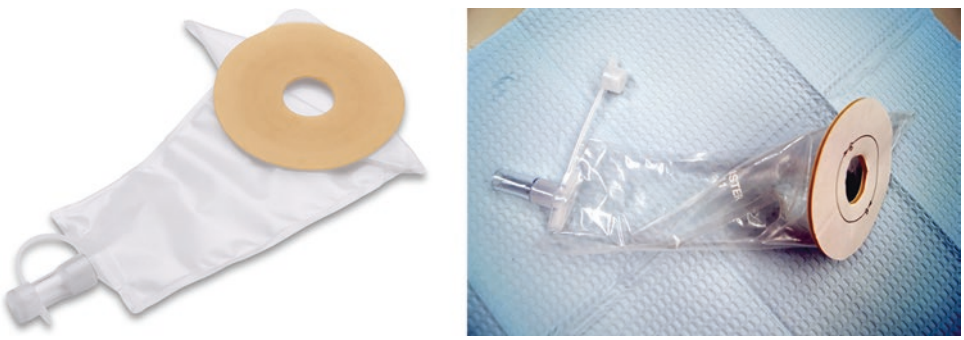


Fig. 3.18 Male adhesive external urinary pouch—Courtesy of Hollister Inc.

within the pouch [10]. The pouch is then applied over the penis and the adhesive is adhered to the pubis (base of the penis).

The female urinary pouch is a one-piece system that encompasses the labia and features an integral adhesive barrier. Training in device application is necessary and actual application can be time intensive, requiring removal of the mons pubis hair and the use of adhesive paste to increase adherence to the perineum. The vulvar opening is measured; the barrier is cut to fit the woman and then adhered to the labia. Problems with leakage persist with these pouches as poor adherence is common, especially in women.

Designs

Designs have not been significantly changed since this device was first introduced [28, 29, 30]. Pieper and Cleland [31] provided a review of external female devices noting that early designs involved a vaginal insert or locator to anchor the device and prevent urine from flowing into the vagina. A urine collection receptacle, which may have resembled a cup-shaped device, was either placed between the labia or suctioned against the meatus. They [31] designed and tested a "female urine collection device" that consisted of a latex periurethral adapter that fit laterally between the labia minora and vertically between the clitoris and vaginal orifice. The drainage part of the adapter surrounded the urethra, adhering with the use of adhesive. However, none of the early designs proved to be effective in collecting urine in women. The ideal device for women would be one that is easy to place and works well for women who are bedridden, who transfer from beds to chairs, or who use wheelchairs. Also, if correctly fitted, urine should not contaminate the skin. Unfortunately, no device has proven to be very useful for women.

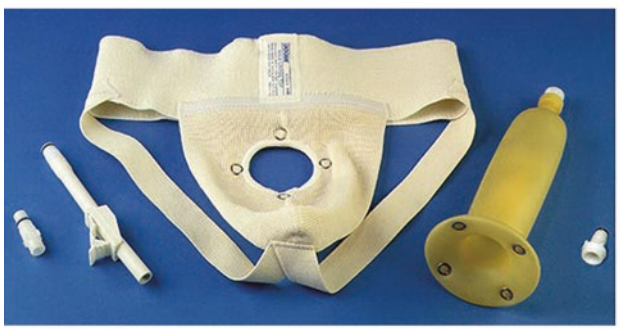
Fig. 3.19 Female adhesive external urinary pouch—Courtesy of Hollister Inc.

Description of External Catheter Containment Systems

In the US, there is growing use of ECCSs that can be washed and reused for weeks to months. These reusable and washable devices are available, primarily for men, and many find them on the internet. These systems are referred to as "bodyworn" products (see Fig. 3.20) or pubic-pressure urinals or devices [12]. They consist of some type of receptacle or cone-shaped device that is fitted over the penis and held firmly in place against the pubis with close-fitting straps, belts or cloth underwear. This pressure allows the penis to protrude into the MEC. The device is attached to a drainage bag. This system is not suitable for overnight use because of urine leakage. They are used by men with slight to moderate incontinence and are designed for men who find other MECs unsuitable.

Reusable ECCS can be easily removed and are popular for episodic wearing (e.g., while traveling, golfing, etc.) (see Figs. 3.20, 3.21, and 3.22). There is also a growing need for ECCSs for men and women in the military who encounter

Fig. 3.20 Reusable external bodyworn containment system (Mc Guire)—Courtesy of Coloplast Corp.



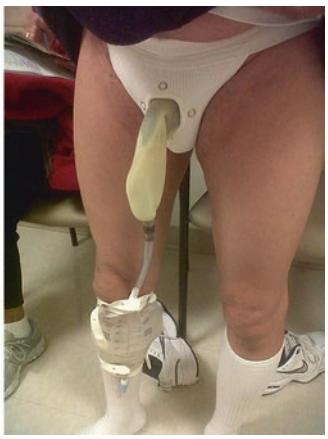


Fig. 3.21 Reusable latex ECCS that consists of a tubular sleeve, which encompasses the penis at one end, has an external fixation Velcro™ strap, and an outlet at the other end. The outlet can be drained by means of a tap. These are also referred to as "drip urinals"—Courtesy of AlphaDry

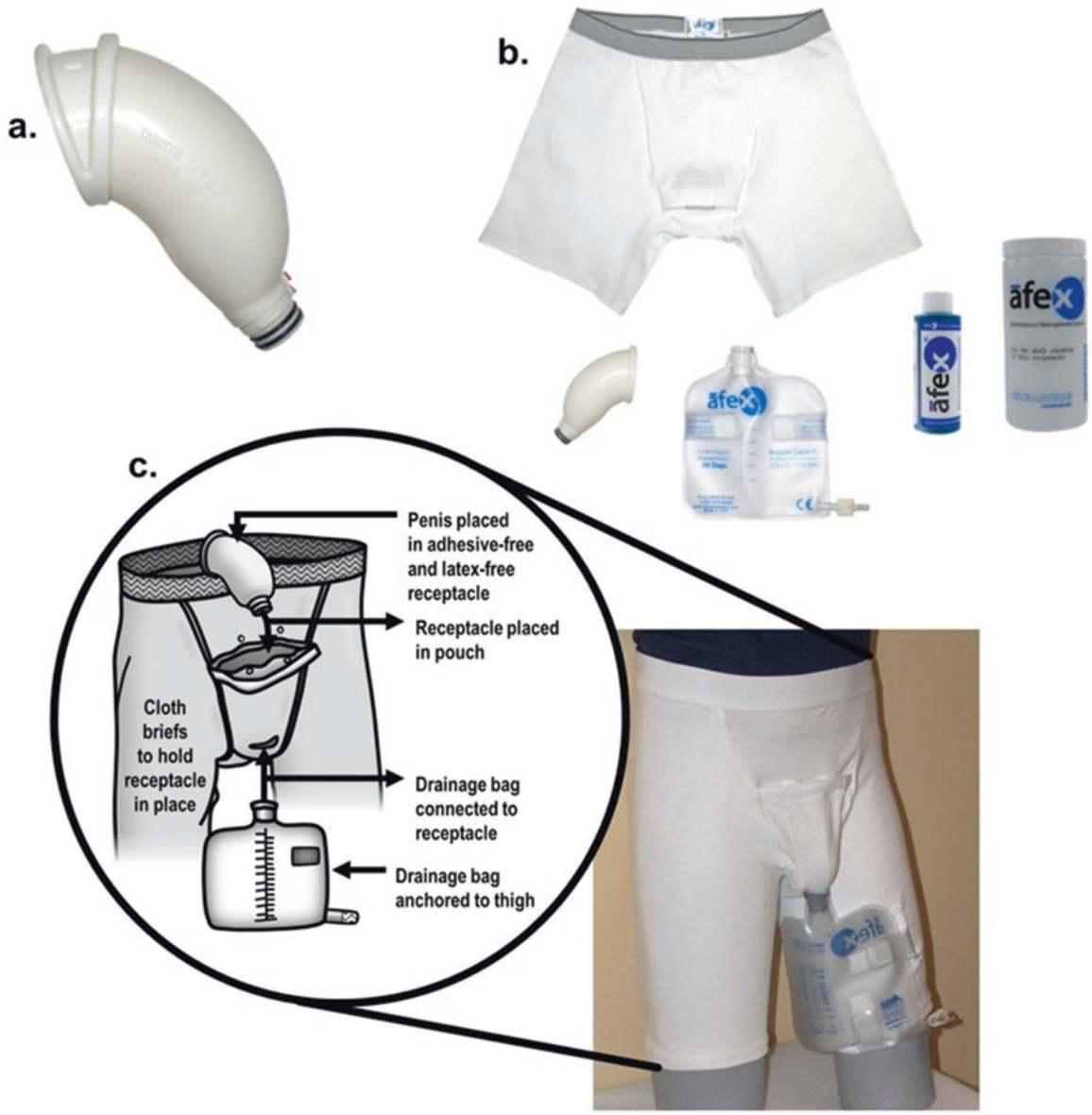


Fig. 3.22 Parts of the AFEX Male bodyworn ECCS—Courtesy of Arcus Medical. Receptacle high style shape is best suited for patients who may be more active or stand for longer periods of time. The high style is also recommended for bedtime use and better suited for men who may be at the threshold for required penis length. The design offers a double wall for back-flow protection and is designed for skin rash prevention. The receptacle is latex free, pressure free, and adhesive free

Fig. 3.23 Bodyworn pubic pressure ECCSs that can be worn in all positions. (**a**) Male Cup: Penis is inserted through the soft foam ring. The cup is made with medical-grade urethane and is latex-free and vinyl-free. Sensors in the cup detect urine. (**b**) The dual chambered collection system reduces skin contact and irritation. The leak-proof hydro-block air filter keeps patient dry and eliminates odor. (**c**) The control device attaches to the chamber with an integrated reflux valve. The control device automatically activates when the sensors in the cup detect urine, and pumps the urine away from the skin. URINCare—Courtesy of Omni Medical Systems

difficulties with voiding while in active war zones [32] or in fighter planes [33]. Newer products are latex-free.

Types

Technological advances are making these products more available and more user-friendly. The main driver for these technological advances has been the military and, in particular, Air Force pilots. Agarwal and Subramaniam [33] developed a set of 56 questions addressing nine areas of pilot concern associated with long duration flying of which in-flight urine disposal was one of the areas. A total of 30 male pilots with a mean age of 30 years were questioned about their preferred method of in-flight urine disposal. Most pilots (80%) agreed that the adult diaper was not an appropriate method for urine disposal and 95% reported never using a diaper for in-flight urination. In aircraft used for long missions, pilots use the negative-G strap, a thick flat strap that presses on the crotch. Urination requires a loosening of the strap, which in the absence of an autopilot, is difficult if not impossible for these pilots. Sixty-six percent reported preferring condom drainage and 100% of these pilots felt that better research is needed for urine disposal.

Von Thesling et al. [37] reported on a male in-flight urine collection device, a reusable latex sheath-style catheter worn throughout flight and affixed during donning of a pressure suit. This device has evolved into sensor-driven technology that actively pulls urine away from the body (see Fig. 3.23).

If male military pilots are finding challenges with urination while flying combat missions, women are equally, if not more likely, to encounter difficulty. Deployment environments generally lack privacy; are crowded living arrangements; have unsanitary conditions; have limited toilet, shower, and laundry facilities; and have increased safety and security concerns [34]. Many women do not use bodyworn ECCSs but rather use a type of urinal (see Chap. 7) [32, 35, 36].

Considerations for Use of MECs

Patient acceptance and cooperation are needed to be successful in using an ECCS. They have been found to be more comfortable, less painful, and less restrictive on activities than other urinary catheters (e.g., IUC) or containment products. Chartier-Kastler et al. [38] reported on a randomized, controlled crossover trial in adult men who were using an

absorbent product (AP) for management of moderate to severe UI. The APs varied in thickness and consistency from patient to patient. Men (n=61) were recruited from 14 outpatient urology centers and 58 men (mean age 66.8) were included in the intent-to-treat analysis. Participants were asked to compare an urisheath with a collection bag to their usual AP. On average, men used a median of 3 APs per day with a median 1-hour pad test of 54.5 grams at baseline. Men were excluded if they had a retracted penis or penile lesions, concomitant fecal incontinence, or were unable to self-apply the urisheath. Two validated questionnaires measured quality of life (QoL); a UI-specific (Kings Health Questionnaire [KHQ]) and a generic QoL questionnaire. All dimensions of the KHQ scored lower for urisheaths indicating an improvement in QoL. This was especially true for limitations of daily and social activities and impact of UI (see Chart 3.1). The majority of patients (69%) preferred the MECs to their usual AP ($P = 0.002$) (see Chart 3.2). Participants rated the MEC significantly higher for all categories (efficacy, feeling of security, feelings of freedom, self-image, discretion, odor management, and skin integrity) except for ease of use, which was significantly higher with the AP (see Chart 3.3).

Assessment prior to EC use should include several parameters and a demonstration of catheter application. An effective ECCS is one that is affordable, stays securely in place for an acceptable period of time, does not leak, is comfortable to wear and easy to apply and remove, does not cause skin breakdown, and effectively channels the urine into a drainage bag [10, 12, 25]. Clinicians need to consider the following when determining if an ECCS is indicated for an individual patient.

- *Mental status*: A confused patient may not be able to manage an MEC and may try to remove the catheter causing tissue injury.
- *Dexterity*: If a patient has difficulty manipulating small objects, ease of application and removal of an ECCS may be an issue. A caregiver or family member who will apply the catheter should be identified. In an LTC facility or acute care setting, staff can be taught to apply these devices.
- *Body habitus*: In addition to dexterity, physical inability to apply the device or to visualize the penis can hinder adequate application [2]. A patient with a high body mass index and a large abdominal girth may have a combined problem—poor visualization of the penis and significant suprapubic fat pad—causing further loss of a visible and accessible penis.
- *Penis width and length*: Size of the penis (width and length or circumference and length) must be sufficient to support the catheter. There should be at least 1.5 in. (3.8 cm) of penile length available. Most MECs available will fit most penis lengths, except for a retracted penis. Some manufacturers have different lengths. With aging and prostate cancer treatments, penile length and size may change, causing the penis to retract (penis disappears into the pelvic cavity). In such cases, it may be difficult to keep the ECCS from dislodging and a retracted penis EP should be considered. The penile shaft circumference should also be measured. If the MEC is too small, it may not fit correctly, fall off or stop urine flow because of urethral compression. If the MEC is too large, it will leak and the urine will loosen the adhesive, causing the sheath to fall off. Problems can also occur if a man has a large glans penis and narrow penile shaft causing channels or ridges along the penis allowing urine backflow, leakage, and dislodgement. In these cases, a two-piece sheath may be more appropriate as the adhesive strips can be applied in a spiral fashion.

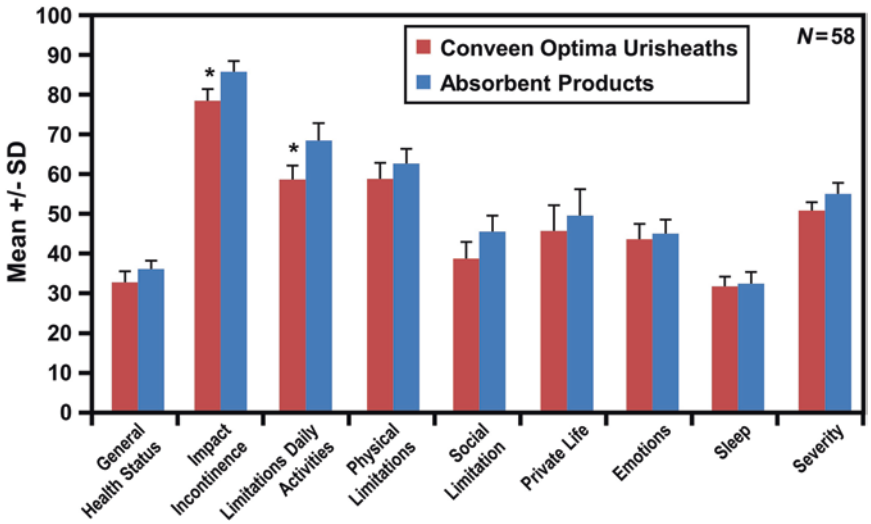


Chart 3.1 KHQ scores. The lower the score, the higher the QoL, **Significant difference* ($P < 0.05$)

Chart 3.2 Patient preference

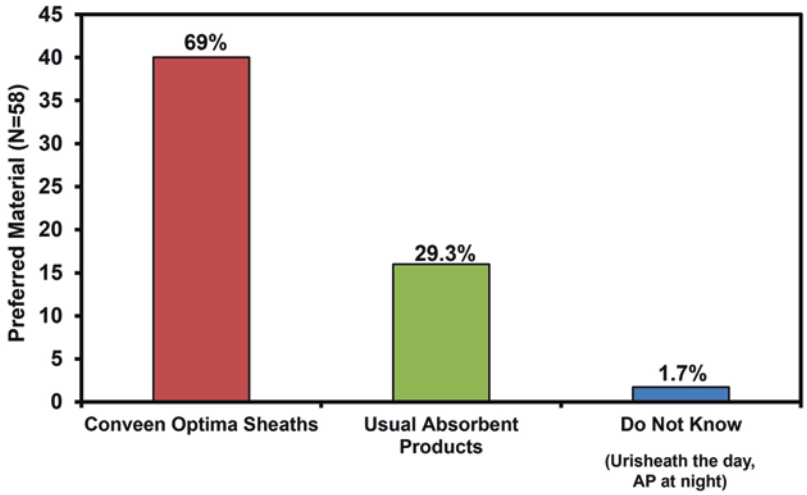
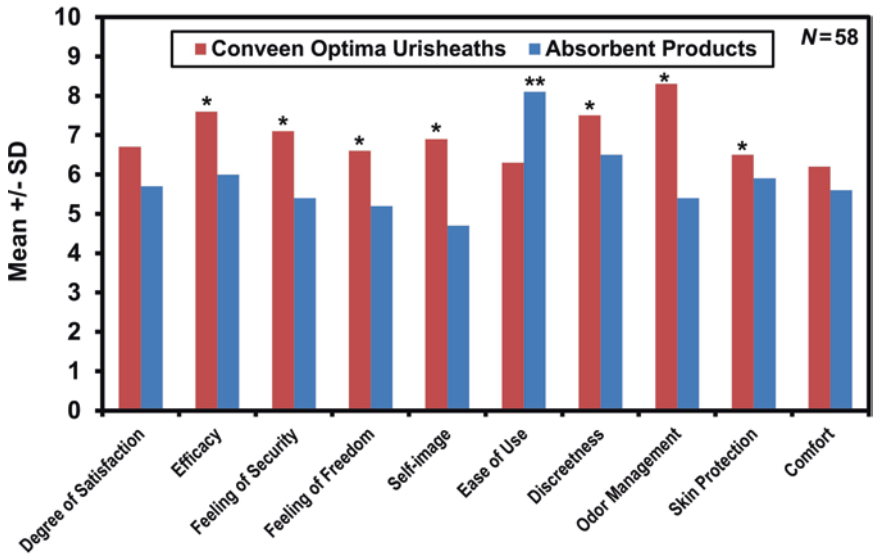


Chart 3.3 Product performance. **Significant difference favor of urisheaths*; *** Significance difference in favor of APs*



- *Penile skin condition*: ECCSs should be considered only in patients who have intact skin. Thus, the penis and scrotum must be assessed for erythema, open areas, and perineal dermatitis (bacterial and fungal rashes). If the patient is at risk for possible skin breakdown, skin-protective films or barrier wipes used for stoma care should be applied to the penile skin prior to placing the device. Do not use a barrier cream on an adhesive-adherent sheath. An attractive feature of silicone ECCSs is that they are made of clear material, allowing for monitoring of skin condition.
- *Allergy or sensitivities:* Determine possible allergies to latex, as many ECCSs have latex in one of the parts, or determine sensitivities to adhesive. An allergic reaction to latex may manifest itself as inflamed, reddened and edematous skin 5–30 minutes (m) after contact with an ECCS that contains latex. Regular ECCS users should be routinely assessed as a latex allergy status can change over time and with continued use [12].
- *Cost*: The price of different types of ECCS varies, with disposable 24–72 h MECs being the least expensive. Medicare will cover 32 disposable MECs per month. Not all insurers provide this level of coverage. Reusable ECCSs have several components and range in price but are generally more expensive.

Application of MECs

The actual application of MECs, reviewed in Table 3.2, can be challenging for nurses, patients, and caregivers. Pemberton et al. [5] compared commonly used MECs and

Table 3.2 Applying a male external catheter

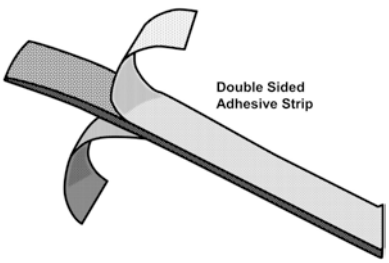
Preparation:

1. Explain procedure to patient
2. Implement hand hygiene before and after application of the sheath. Put on gloves
3. Assess for adequate penile length to support the MEC; if not adequate, consider an external pouch or a glans-adherent external device. Length should be at least 2 cm for successful fixation. A retracted penis will limit MEC options, so a retracted penis pouch or glans-adherent external device may be more appropriate
4. Prepare skin: Wash penis with soap (not moisturizer) and water. Do not apply moisturizer as the adhesive will not stick. Allow penis to dry. A protective wipe may be used
5. Assess the condition of the skin for any irritation, swelling, and breakdown. If skin irritation is present but skin is not broken, consider applying a skin barrier product prior to the placement of the device to protect the penile skin from breakdown caused by repetitive application and removal of an adhesive device. If the MEC material is silicone, skin products may reduce the adhesiveness of the MEC
6. If needed, trim any hair around the penis and its base so hair will not stick to the adhesive
   - Using a protective cloth or paper towel with a hole cut in it can keep hair out of the way when fitting the sheath
7. There are several sizes of MECs, so the use of a measuring or "sizing" guide supplied by manufacturers is recommended. Place the measuring guide at the circumference (the widest point) of a non-erect penis gently extended away from the body. If the penis is between two sizes, select the smaller size
   - When choosing a size, allow for nocturnal erections
   - There are MECs available in different lengths

Application:

- Self-adhesive one-piece MEC: adhesive film on its internal surface attaches the MEC to the penile shaft. This catheter is then rolled up the shaft and fixed in place. Place the catheter on the head of the penis, keeping ¾–1 in. between the penis and tip or distal end of the catheter. Unroll the MEC down the penile shaft. Some have a pull-tab or applicator on the catheter that assists in unrolling the catheter towards the base of the penis

- Non-adhesive two-piece MEC: an adhesive double or single-sided strip attaches the catheter to the penis. The adhesive strips are placed onto the penis (encircling it) and the MEC is rolled over the penis, attaching it to the adhesive strips
  – Unroll the sheath as completely as possible to minimize residual roller ridges, ripples, and wrinkles that can cause tissue compression

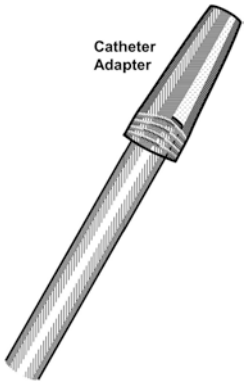


1. Both types of MECs should always be applied leaving a ¾ - 1 in. gap between the tip of the penis and the funnel of the MEC to allow for urine to flow without the MEC "kinking" or "ballooning," which could result in leakage or the EC falling. This also reduces the risk of skin irritation or ulceration from direct contact or pressure on the glans

(continued)

Table 3.2 (continued)

2. If the patient is not circumcised, the MEC is applied over the foreskin except for non-penile sheath, glans-adherent external device
3. Do not allow a roll of the MEC to occur at the base of the penis since this can easily cause ulceration and pressure under the penile shaft
4. Gently squeeze the MEC around the shaft of the penis for a few seconds as the heat of the hand will ensure adhesion
5. Use of a medical adhesive (used when applying ostomy bags) can be applied around the penile shaft to insure that the catheter "adheres" to the penis. The adhesive must be dry before rolling on the catheter
6. Monitor skin for pressure and ulceration. Examine for tightness; the fit should be snug but not constrictive
7. Once in place, obtain a plastic connector tube or catheter adaptor for connection to the drainage bag
8. The bag will be either a smaller capacity leg bag or larger capacity drainage bag. A smaller bag may be used during the day and a larger one at night. The leg bag needs to be attached properly, in order to allow urine to flow into the bag without difficulty. It can be placed at different positions on the leg (thigh, calf, knee); and is most commonly fastened around the thigh or calf with two straps or a sleeve to hold the bag safely in place while providing comfort in use (see Chap. 5)
9. MECs should be changed daily and a thorough inspection of the penis should be done to ensure skin integrity. If needed, use warm water or adhesive removal to aid in removing the MEC; do not use alcohol, acetone, or similar solvents to remove adhesive



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found that ease of use and application with gloves were important in assessing a person's ability to apply them. If the person applying the MEC has difficulty with dexterity, an MEC that has an applicator or strip that assists the patient or caregiver in rolling on the MEC should be considered (see Fig. 3.8). Constrictive objects should never be applied to the penile shaft circumferentially (e.g., adhesive tape, string, rubber band), because they may cause pressure and ulceration, especially in a patient with diminished perineal sensation. Once a patient is fitted for an MEC or any type of ECCS, regular follow-up should be scheduled to determine compliance and correct use. See the Patient Education Tool for instructions on applying an MEC.

There are several different sizes of MECs with diameters ranging from 21 to 40 mm, in 5- to 10-mm increments therefore, it is important to select the correct size. The use of a placement ring or sizing guide (e.g., a card with cut-out sections in various sizes), available from manufacturers of these products, should be used to identify the correct size MEC (see Fig. 3.24). To measure, the circumference of the penis should be completely relaxed. Have the patient sit on the end of a bed or chair. Extend the penis by gently pulling it forward, away from the body. The measurement guide should be placed on the top of the penile shaft, not on the underside, and at the shafts widest point. If the size of the penis is between two sizes on the guide, select the smaller of the two. MEC materials are sufficiently flexible and allow the penis a snug but not tight fit. Choosing the larger of two sizes might result in urinary leakage. The clinician should note erectile function because sizing should allow for nocturnal erections. Most disposable MECs have two different lengths, standard and short (see Fig. 3.27). If penile length is less than 5 cm, a short MEC should be used. It is more important to determine the exact diameter of the penis to fit the correct size of the MEC than the length of the penis. Some reusable bodyworn ECCSs may be effective for men with a retracted, shorter length penis.

The catheter should be examined for tightness; fit should be snug but not constrictive. If the catheter sheath wrinkles, a smaller size should be tried. If urine leaks, the sheath can be squeezed for better seal. A medical adhesive, commonly used when applying ostomy bags, can be applied around the circumference of the penis to ensure that the catheter "sticks" to the penis. The adhesive must be dry before rolling on the catheter. A skin barrier product can be applied to the penis to protect penile skin from breakdown secondary to repetitive application and removal of an adhesive device. Table 3.3 lists common problems seen with MECs.

Adverse Events

Complications related to ECCSs primarily involve external penile shaft problems, seen in 15–30% of patients [39]. These have been categorized as irritative, allergic or compressive. Constriction of the penis is seen in 15% of long-term users [39]. Most adverse effects seen are the result of improper and prolonged EC use and are more pronounced in men who have decreased penile and scrotal sensation [19]. But many of reported cases of complications are from older ECCSs that are no longer available. Complications occur more frequently in developing countries.

Urinary tract infection (UTIs) can occur but are less likely than with internal catheters (indwelling or intermittent) because ECCSs avoid invasive instrumentation of the urethra UTIs may occur in 40% of long-term MECs users

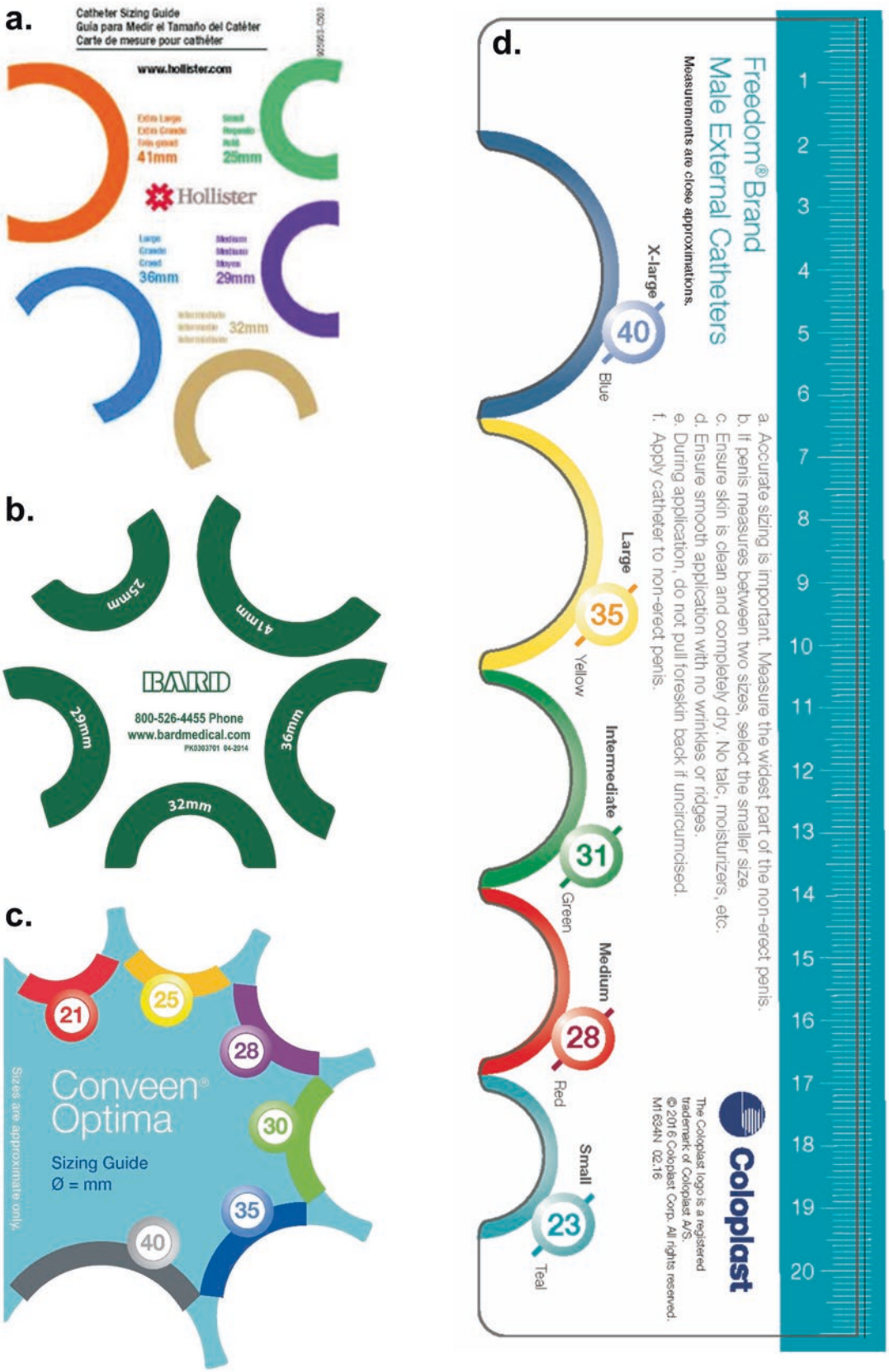

Fig. 3.24 Disposable MEC sizing guide. (**a**) Courtesy of Hollister Inc. (**b**) Courtesy of C.R. Bard, Inc. (**c**) and (**d**) Courtesy of Coloplast Corp.

Table 3.3 Troubleshooting male external catheter problems

Problems	Possible reasons	Considerations
Pressure sore on the shaft of the penis	• MEC is too small • Pressure from the adhesive strip or tape is too strong	• Select a larger size MEC • The adhesive strip or tape should not be applied in a circular but a spiral pattern • Consider switching to a reusable system that does not use adhesive on the shaft
Pressure sore at the foreskin	• Pressure from the MEC is too high (e.g., due to an erection)	• Unroll the MEC 4–6 cm to ensure that there is sufficient space between the foreskin and the tip of the MEC • Consider switching to a reusable ECCS that does not use adhesive on the shaft
Drainage problems—urine flow disrupted	• Sheath size too small • MEC is trapped beneath the elastic trim of the undergarment clothes • Clothing is too tight • Tube is too long or kinked • Bag is not secured properly or not positioned correctly • Bag contains air	• Select more loose fitting clothes • Check the tube • Check the leg bag for security and position • Replace the drainage bag
Sheath dislodges within a short time after application	• Sheath size is too big • Urine is loosening the adhesive	• Re-measure size of penile shaft • Ensure proper application
Urine leakage	• MEC does not fit well (too large) • Hair may be caught between the MEC and the skin—thereby producing small leakages • Penile retraction is present • UTI • Sweating	• Measure again and select the correct size • Trim pubic hair • Try a different MEC • Avoid kinking or twisting of the urisheath or bag as this allows urine to pool and weakens the adhesive
Connecting tube keeps slipping away from the MEC	• Connecting tube and the MEC are not compatible	• Choose compatible materials • Use an adapter between drainage tube and MEC • Ensure the connecting tube is inserted into the funnel end of MEC securely to avoid dislodgement
Skin breaks or irritated	• Sensitivity/allergy for skin care products or material (e.g., latex) • Prolonged use of adhesives • Use of powder	• Replace MEC with one made of different material (e.g. silicone) • Use a different brand of adhesive • Consider applying a barrier film product on penile shaft device • Make sure that all hair on the shaft and base of the penis are trimmed so they won't stick to the adhesive tape on the inside of the catheter, increasing folliculitis and skin irritation
Skin too damp	• MEC was applied too soon after a bath or shower • Sweating	• Ideally, wait at least 15 min after a shower or a bath before applying the MEC • Consider switching to a reusable ECCS that does not use adhesive on the shaft

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[13, 40]. Saint et al. [13] demonstrated an 80% reduction in UTIs with men using an external catheter when compared with those men using an IUC, despite the fact that MEC-associated bacteriuria may represent contamination. Grigoryan et al. [41] demonstrated that urine from MECs had fewer biofilm-forming bacteria than urine from IUCs.

Skin irritation and breakdown (i.e., dermatitis, erosion, maceration, minor skin erosions) can be caused by several factors. Causes include: too tight MEC; excessive or uneven adhesive, frequent device changes, pulling off a MEC causing tearing of the skin, latex allergy, and a UTI. A too tight MEC can lead to occlusion of the penile shaft or pubic area. Erosion of the penile skin, maceration, and irritation can also be caused by friction [42]. Chronic irritation can be caused by urine leakage around an ill-fitting device and lead to maceration, ulceration, and subsequent appearance of polypoid masses. In these cases, one should consider applying a liquid polymer acrylate (liquid skin barrier) product or wipe to protect the skin prior to application of the catheter (see Chap.8). External catheter-related contact dermatitis can cause penile edema, and dermatitis of the penile shaft and scrotum. In severe cases, epidermal sloughing of the entire shaft may occur. Severe complications (e.g., necrosis, gangrene) have been seen. Sensitization to thiurams in latex can cause long-term complications in men using latex ECCSs [43].

To prevent skin irritation when removing the sheath, wrap a warm cloth around the sheath to soften and loosen the adhesive or remove the sheath when bathing. Always roll the sheath back when removing.

Clear ECCSs allow visualization of the skin beneath without removing the catheter (see Fig. 3.25). Clear MECs are silicone which has water and oxygen vapor transmission properties that allow the skin to breathe [21]. If skin breakdown occurs, the ECCS should be removed for the skin to heal. Before returning to using the catheter, the person or caregiver should determine why the breakdown occurred (e.g., sheath too tight, sheath pulled off, tearing of the skin, possible latex allergy, UTI). In men who are at-risk for or develop skin issues caused by an EC, applying a barrier skin product before application should be considered.

Fig. 3.25 Silicone MEC, InView—Courtesy of Hollister Inc.

Catheter fails to stay in place, "falls off," "pops off": there are several reasons why an MEC may prematurely become dislodged and fall off. The most common reason is that the sheath has been fitted incorrectly (e.g., wrong size, less than a 360° seal). An incorrectly sized and fitted sheath can also cause several adverse events leading to dislodgement (see Fig. 3.26). The catheter can twist or kink preventing the urine from draining and allowing the urine to pool at the meatus (see Fig. 3.27). The sheath may "balloon out" if urine is being voided. Back-flow of urine may occur, weakening the adhesive and leading to catheter leakage. If the patient finds the ECCS uncomfortable, the patient may manipulate the system leading to urine leakage or the device falling off. An ECCS also may not stay in place in the case of a confused patient who does not know why the sheath is on. Avoid external catheter use in these patients [6].

Use of stoma adhesive on the penile shaft may improve adhesion. Avoid using powders or creams as these will prevent sheath adhesion.

Penile complications include:

- *Paraphimosis* is present when the orifice of the foreskin is constricted, preventing retraction of the foreskin over the glans. This can occur as a result of overconstriction of the penis from an external device rolled over the penile shaft. Circumcision may be required.
- *Constriction or strangulation of the penis* is rare but if it occurs, it can lead to penile necrosis [44] and gangrene [45, 46]. The continuous tourniquet effect of an MEC on a penis, especially when using an external or internal strap for fixation, is usually the cause. The tourniquet effect causes penile engorgement from the decrease in venous and lymphatic drainage. If not relieved, arterial flow may be compromised resulting in edema, ischemia, and gangrene [47]. Figure 3.28 shows a patient who used gauze pads to secure an MEC, causing significant

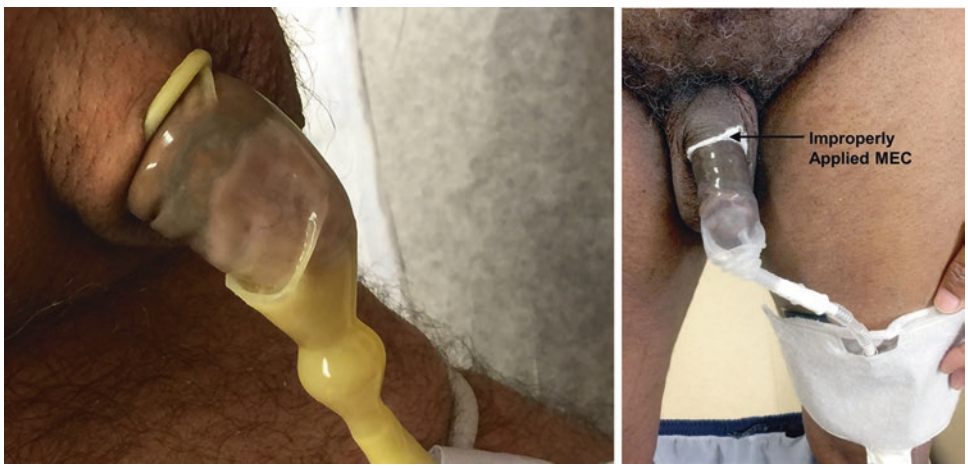

Fig. 3.26 Improperly applied MEC

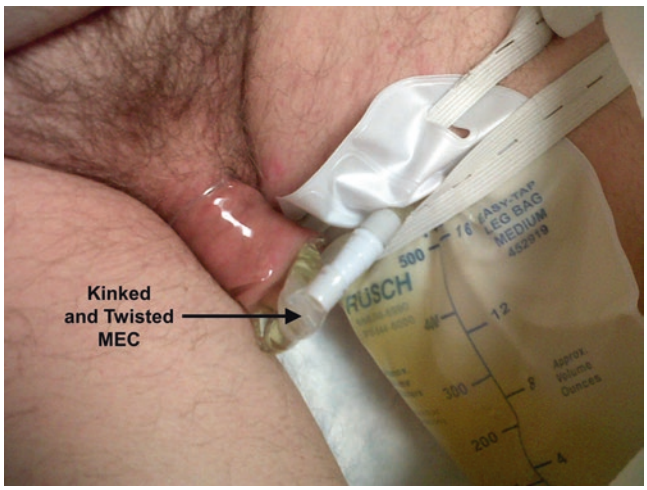

Fig. 3.27 Twisted/kinked MEC causing pooling of urine at the tip

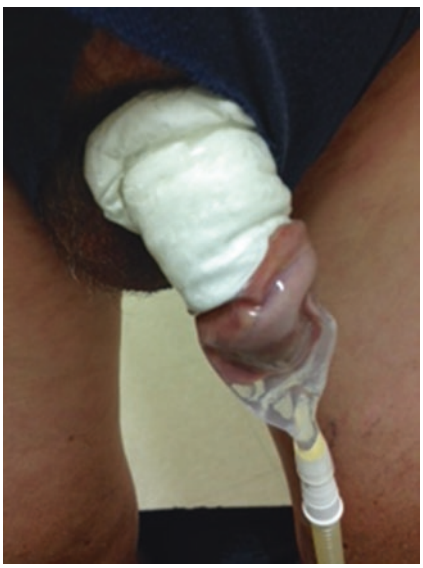

Fig. 3.28 Gauze tourniquet used to secure MEC. Penile edema and phimosis evident

constriction of the penile shaft and leading to penile edema and phimosis. This complication is seen more often in patients with a spinal cord injury, who may lack nociceptive feedback and be unaware of painful sensation from the tourniquet effect. Debridement, total penectomy, and skin graft reconstruction may be necessary.

- *Urethral diverticulum* is another rare complication. It has been reported secondary to ischemic atrophy of the underlying corpus spongiosum from a reconstructive double-sided adhesive strap [48].
- *Lymphedematous fibroepithelial polypoid benign masses* of the penis are rare but have been reported in patients with a spinal cord injury secondary to chronic irritation due to urine leakage around an ill-fitting long-term external device [49–53].

Evidence-Based Research

There are very few published studies comparing available ECCSs. Evidence on the effectiveness of external catheters in relation to catheter adherence and detachment is lacking. Earlier research was performed primarily on disposable MECs, most of which are no longer available. A 1998 study conducted on six different self-adhesive MECs found substantial differences in performance between products [19]. In 2003, Paterson et al. [54] performed semi-structured interviews and focus groups of men and women with incontinence and their caregivers to determine concerns with incontinence products in order to inform and develop an Australian consumer guide to continence products. Men complained that penile sheaths "do not last a full day, they fall off, don't stick" and that drainage bags leak (p. 960). Since then, designs of disposable MECs have changed and the availability of reusable MECs has increased in the US.

Most research has been conducted on men in the VAMC who report that an MEC is more comfortable, less painful, and less restrictive on their activities than other devices (e.g., IUCs). A study by Saint et al. [16] indicated that nurses also preferred MECs to IUCs.

Conflicting results in the few available studies have left the role of MECs in hospitalized patients or LTC residents unclear [13]. Saint et al. [13] compared IUCs with MECs in male inpatients in a VAMC. Seventy-five subjects were randomized: 41 receiving an IUC and 34 an MEC. The incidence of an adverse outcome was 131/1000 patient-days with an IUC versus 70/1000 patient-days with an MEC. The median time to an adverse event was 7 days in the IUC group and 11 days in the MEC group. Reduced adverse outcomes were seen in men with MECs, including bacteriuria, symptomatic UTI, and death. This protective effect was seen primarily in men who did not have dementia. The men in this study also noted that an MEC was more comfortable and less painful than an IUC.

Macaulay et al. [55] in the United Kingdom (UK) conducted a randomized cross-over trial of men with stress UI post prostate treatment (e.g., radical prostatectomy, TURP, radiotherapy) to test three products (penile clamp, MEC, absorbent product) in random order during the day and night (except clamp) for up to 3 weeks. Participants used the standard care incontinence absorbent product, a perineal

Fig. 3.29 Clear silicone integral adhesive—Courtesy of C.R. Bard, Inc.

Fig. 3.30 Bodyworn pubic pressure external devices with waist strap, belt, or leg straps

pad, supplied by the UK National Health System. The most commonly used MEC brands selected included a one-piece integral adhesive MECs (see Fig. 3.29) and a one or two-piece bodyworn device (see Fig. 3.30). Men were fitted by representatives of UK suppliers. The penile clamp used was the Cunningham clamp (see Chap. 7). Interestingly, while more than half of participants had previously tried urisheaths, few had used a bodyworn device or a clamp. The participants were asked to complete an Overall Opinion Questionnaire to determine overall product acceptability, advantages, disadvantages, and preferences, using a visual analogue scale. A total of 74 men consented to participate in the study, but 23 withdrew after consent, and 12 withdrew during testing, leaving 56 men (mean age 72.2 years) who completed the study. As to severity of UI, 67.9% reported light urine leakage and 32.1% report moderate/heavy leakage. Participants rated incontinence pads significantly higher than the other products in all situations. Pads were the easiest product to apply and remove and were very comfortable when dry, but were reported to leak the most. Urisheaths were more acceptable than the bodyworn device. Urisheaths were rated better than pads for leakage, odor, comfort when dry (but not when wet), ease of carrying, and disposal. When compared to the pads, the bodyworn device was rated higher for comfort when wet but worse than the sheath in all other aspects. An advantage of the bodyworn device was that it was washable and could be used for long periods of time without changing. The clamp caused the most pain (N = 47) but was rated better than the other three products for security, leakage and low impact on clothing choice. An important finding in this study was that men used a combination of products such as a penile clamp during the day and a pad or urisheath at night. This is commonly seen in clinical practice.

Patient Information

- *How to Use a Male External Catheter Patient Education Tool*

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How to Use a Male External Catheter Patient Education Tool

What Is an External Catheter?

An external catheter is used by a man to collect urine that leaks from the bladder (called "urinary incontinence"). These catheters are also called "urisheath" or "condom" or "Texas" catheters. This catheter is used on the outside of the body, as it fits over the penis, and connects to a drainage bag.

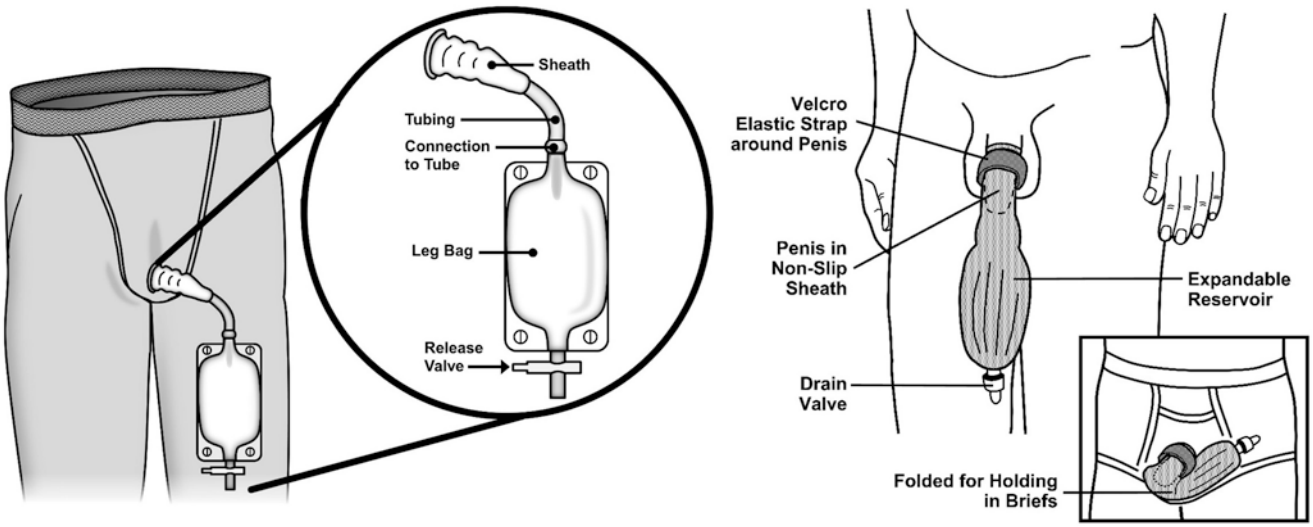
Types of External Catheters

There are several types of catheters to choose from. They can be used once or reused many times.

External Catheter with Adhesive

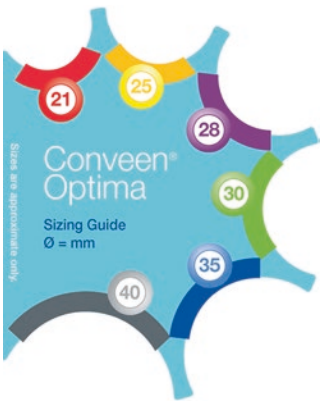
Male Urinary Pouch

1. The most common type has adhesive on the inside of the catheter as shown in this picture. It is rolled on, over the penis, and the adhesive allows it to stick to the skin of the penis. This catheter must be replaced every 1–2 days or sooner if it falls off.
2. Another type of disposable external catheter is called a male urinary pouch. This pouch has adhesive and a pouch that is attached to the drainage bag. The pouch can be used by men whose penis may have "retracted" (pulled in and shortened) or who cannot or will not be fitted by other external products.
3. A third type is shown in pictures below. The catheter is held against your body with cloth underwear, a belt or with straps. This type can be washed and reused.



Putting on a Disposable External Catheter

First, read the manufacturer's information. To find the correct catheter size, measure the diameter or circumference of your penis with a fitting or sizing guide like the one shown here. It is worth trying different systems to find the one that best fits your needs.

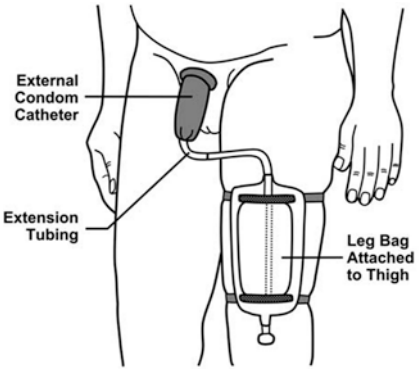


- Wash your hands. Then gather your equipment: correctly-sized catheter, leg drainage bag with extension tubing, straps, manicure scissors, soap, washcloth, towel, and protective ointment.
- Trim the hair on the base of your penis or any other hair so it won't stick to the adhesive tape on the inside of the catheter. Do not shave your hair, clip it.
- Before each catheter change, wash, rinse, and dry your penis. To protect your skin from urine, you may want to coat your penis with protective skin barrier product and let it dry (it will feel sticky). This skin product will protect your skin from perspiration and urine. Moisture softens your skin and makes it more likely to tear or open when you remove the catheter,
- Make sure the sheath is tightly rolled to the edge of the connector tip, balloon-like part seen in this picture. You can squeeze the catheter below the adhesive part to make it easier to apply.
- Next, hold your penis and place the catheter on the tip of your penis. Gently stretch your penis as you unroll the catheter over the head of your penis and down your penis.
- Leave about half an inch of space between the tip of your penis and the end of the sheath at the connector tip, so your penis does not rub against the end of the catheter.
- If you are not circumcised, leave your foreskin in place and roll the catheter over your foreskin. Your foreskin may swell if it is not kept over the head of the penis. The catheter should be snug when rolling it on. If it is loose, the catheter may be too large. If you are unable to unroll the catheter down the penis, the catheter may be too small.

Applying Rolled Sheath (Catheter)

When the catheter is unrolled, gently press it against your penis so that it sticks. Put pressure on your penis for several minutes to be sure any wrinkles are sealed together and to get rid of air bubbles.

- Connect one end of the tubing to the open connector tip on the catheter and the other end to the extension tube attached to the drainage bag.
- If the extension tube is too long, cut it to the length you want.
- Leg bags come with elastic straps so attach the drainage bag to your thigh as shown in this picture or to your lower leg. Do not use too large a leg bag that is too large, because it will put too much weight on the catheter, causing it to fall off.
- You may need to clean the bag twice a day.
- The catheter is only used once and is to be discarded once removed. It will be need to be changed daily.



Solving Problems with Your External Catheter

- If the catheter doesn't stick, make sure your penis is completely dry before putting on the catheter. Use only ointments and adhesives prescribed by your doctor or nurse.
- Don't wash with Betadine because this can irritate your skin.
- If urine leaks around the catheter, squeeze the catheter to get a better seal or consider a smaller size. A too large catheter will cause urine to leak out between the catheter and your penis.
- If the catheter is too snug or tight, it may cause the skin of the penis to break open. If it is too tight, you may need a larger size. If it is loose or there are a lot of wrinkles, the catheter may be too large. That is why it is important to find the correct size for you.
- If the catheter sheath wrinkles, it may be too large and you will need to select a smaller size.
- Check your penis daily or more frequently for swelling or unusual color. If it feels uncomfortable or doesn't look normal, take off the catheter and call your doctor or nurse.
- Call your nurse or doctor if you:
  - Feel pain or burning when you urinate;
  - Have the urge to urinate very frequently;
  - Smell an unpleasant odor from your urine; or
  - See blood or pus in your urine.

Ureteral Stents, Nephrostomy Tubes, and Urethral Dilators

4

Phillip Mucksavage

Overview

This chapter examines ureteral stents, percutaneous nephrostomy tubes, and urethral dilators. The chapter defines each device and and describes, indications for use, materials, designs, and placement techniques. Complications and methods to avoid morbidity are also discussed.

Ureteral Stent

Ureteral stents are an integral part of many urologic surgeries and procedures.

Definition

A ureteral stent is a thin catheter or tube inserted into the ureter to ensure genitourinary (GU) tract urine flow. The term "stent" is described in most medical textbooks as a device used to maintain a bodily orifice, cavity or contour, or as a catheter, rod or tube within a tubular structure to maintain luminal patency or protect an anastomosis [1]. The origins and usage of the word "stent" in urology are actually very recent. In the past, "splint" and "stent" were often used interchangeably to describe the same technique or device. In 1972, Goodwin wrote a brief article entitled "Splint, Stent, Stint," noting that when urologists place a tube in the ureter or urethra, "it may be a stent. It probably is never a stint" [2]. Finally, in 1973, the term "stent" was solidified in the urological lexicon after an article by Montie et al. [3] noted "when referring to an intraluminal device to maintain patency until healing has taken place, the stent is the most appropriate." Since then, the term ureteral stent often refers to a device or tube that is placed in the ureter to maintain ureteral patency, aid in ureteral identification, and/or relieve an obstruction.

Ureteral stents are most commonly used as a temporary method to relieve an internal or external ureteral obstruction. An internal ureteral stent, often called a "double-J stent," is a device that aids in draining the upper tracts directly into the bladder [4] (see Fig. 4.1a). No portion of a double-J stent is seen externally (See Fig. 4.1b). Ureteral stents are often placed in a retrograde fashion (from the bladder to the kidney) during an endoscopic procedure; however, they can also be placed during percutaneous (directly into the kidney from the flank), open, laparoscopic, or robotic surgery. A ureteral stent may also be placed in an antegrade fashion (from the kidney to the bladder) during surgery, but this is less common. In some instances, a temporary external ureteral catheter may be placed into the kidney from the bladder to allow for: identification of the ureter during surgery, to perform diagnostic imaging and to collect upper tract specimens. These devices exit the urethra and drain into external collection bags (see Chap. 5). Since these types of drainage tubes are easily dislodged, they are usually removed at the end of a procedure or prior to discharge from the hospital. Table 4.1 summarizes types of ureteral stents.

Indications

There are multiple indications for the use of ureteral stents (see Table 4.2). The primary purpose for these devices is to allow for the temporary relief of ureteral obstruction due to intrinsic or extrinsic sources of obstruction [5]. Intrinsic causes of obstruction commonly include ureteral stones, blood clots or tumors, ureteral strictures, and ureteropelvic junction (UPJ) obstruction. Extrinsic obstruction can result

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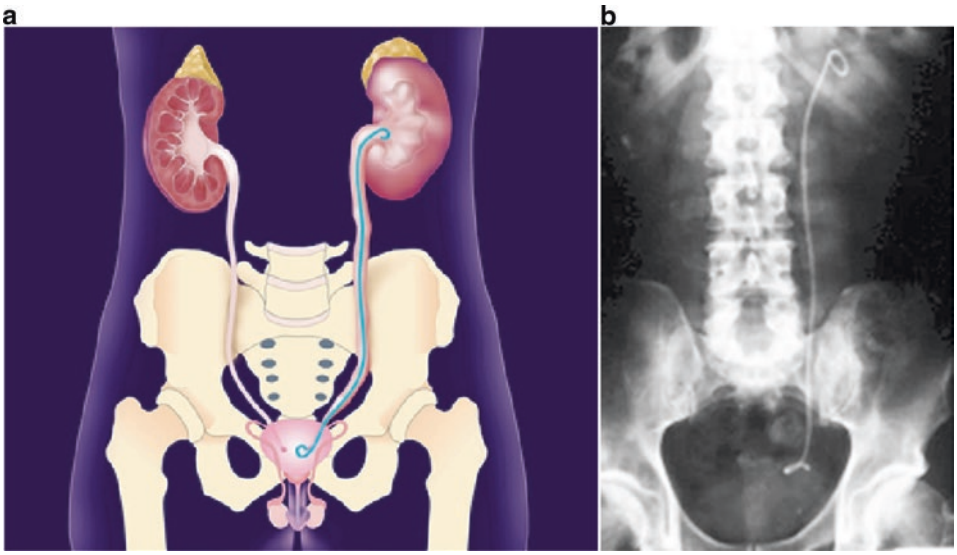

Fig. 4.1 (**a**) is a depiction of a double-J stent in the left kidney. Images Copyright Visible Health, Inc., created using draw MD Urology (www.drawmd.com) and reproduced with permission by Visible Health. (**b**) X-ray image shows the proper position of a double-J ureteral stent

Table 4.1 Types of stents

Device	Description	Application	Complications	Considerations
Indwelling Double-J® or double pigtail stent	• Provides a self-retaining capability due to a double coil ("J-shaped) at the proximal and distal ends that work to securely anchor the stent in the upper urinary tract (renal pelvis and upper calyx) and the bladder • Both ends have multiple side holes that allow urine to drain freely from the kidney's upper collecting system, down through and around the stent, and into the bladder • The use of a string attached to the distal coil of a pigtail stent can also be used to facilitate stent extraction without requiring a cystoscopy • Stent migration is prevented proximally or distally despite urinary flow, patient movement, and ureteral peristalsis	• Double-J® or pigtail stent is a catheter or tube placed within the ureteral lumen in a retrograde or antegrade fashion in order to maintain its patency • Passed cystoscopically to reside within the ureter • A guidewire is removed from the core of the stent • Indication is to relieve upper tract obstruction from any cause	• Stent discomfort • Hematuria (25%) • Irritative voiding symptoms including frequency (50–60%), urgency (57–60%) secondary to the presence of the stent • Dysuria (40%) at the end of voiding may be due to trigonal irritation by the distal end of the stent when it crosses the midline or forms an incomplete loop • Incomplete emptying (76%) • Flank pain (19–32%) due to result of urine reflux towards the kidney that leads to an excessive rise in intrapelvic pressure that ultimately translates into pain • Suprapubic pain (30%) can result from local bladder irritation by the distal coil or as a secondary sign of associated complication such as encrustation or infection • Incontinence usually accompanies urgency	• Can remove a stent with extraction strings located at the distal end of the stent which extends though the meatus of the urethra • Daytime frequency distinguished by the lack of coexisting nocturia suggests that mechanical stimulation relates to physical activities and/or awareness of this stimulation during the day, which would not be significant during the night • Stent length plays a role in stent-related symptoms since it is directly related to bladder irritation • Stent migration can cause trauma, inflammation, and pain • Follow-up care can be neglected for many different reasons: transfer to another provider who is unaware of the stent's presence; provider forgetfulness; and patient failure to seek follow-up care. Consider keeping a "stent registry" to ensure routine follow-up
Ureteral catheter (open-ended, whistle tip, cone tip, olive tip)	• Wide lumen so it can be passed over a wire • Used to inject contrast during radiographic tests • Used to collect urine from the upper urinary tract	• Perform retrograde pyelography • Identify the ureters during pelvic or intestinal surgery • Bypass partial or complete obstruction	• Hematuria • Urosepsis	• Used mostly in the operating room or in interventional radiology

Courtesy of Diane K. Newman; Bailey L & Jaffe WI. Obstructive uropathy. In DK Newman, JF Wyman, VW Welch (Eds). Core Curriculum for Urologic Nursing (1st ed., p. 410, 2017), Pitman, NJ: Society of Urologic Nurses and Associates, Inc.

Table 4.2 Indications for ureteral stents or percutaneous nephrostomy tubes

Indication	Causes
Intrinsic obstruction	Stones Ureteral/bladder tumors UPJ obstruction Blood clots Fungus ball Ureteral stricture Ureteral polyps Sloughed papilla Cholesteatoma
Extrinsic obstruction	Malignancy Retroperitoneal fibrosis Hydronephrosis of pregnancy Abscess Hematoma Vascular anomalies Constipation/fecal impaction Iatrogenic injury
Post procedural	Pyeloplasty Ureteralcalicostomy Uretero-ureterostomy Trans uretero-ureterostomy Ureteral enteric anastomosis Ureteroneocystostomy Renal transplant Ureteroscopy Percutaneous renal surgery
Other	Ureteral identification intraoperatively Renal/ureteral specimen collections

from malignancy (e.g., gynecologic, pelvic) outside of the ureter, retroperitoneal fibrosis, pelvic radiation, or other causes of external ureter compression [6] (see Fig. 4.2).

Ureteral stents may also be placed to promote healing of the ureter after reconstruction. This includes post-surgery for UPJ obstruction, renal transplantation, ureteroureterostomy, ureteroneocystostomy, cystectomy and urinary diversion, as well as after trauma, such as ureteral perforation during ureteroscopy. Following a cystectomy, ureteric stents can help reduce postoperative complications like extravastation, fistula formation and anastomotic stricture. Figure 4.3 shows ureteric stents coiled in the renal pelvis to prevent them moving out of place and protruding through the ileal conduit.

There are absolute indications for ureteral stent placement. These include relief of obstructing pyelonephritis, bilateral obstructing stones, obstruction of a solitary kidney, ureteric injuries (perforation/transections/avulsions) or after surgical repair of the ureter. Relative indications include the relief of pain from an obstructing stone, hydronephrosis or renal colic during pregnancy, significant ureteral edema after ureteroscopy, and before or after shock wave lithotripsy to aid in stone passage.

Materials

The ideal ureteral stent material should quickly improve or restore urinary flow, resist migration, be biocompatible, radiopaque, easy to insert, maintain its strength, be resistant to encrustation and infection, and cause little discomfort or distress to the patient [7]. Despite over 100 years of research into the design and creation of ureteral stents, modern stents that include all of the above criteria have not yet been developed.

Most modern ureteral stents are composed of synthetic proprietary polymeric biomaterial. One of the first synthetic polymers used for the creation of ureteral stents was polyethylene. Polyethylene is flexible and nonreactive in the body; however, long-term exposure to urine causes it to become brittle, which can lead to fragmentation [8]. Silicon stents, which are very biocompatible, were also developed early on, but are difficult to place due to high coefficients of friction and are easily occluded [9].

Manufacturers have produced synthetic compounds of various copolymers with differing strength, surface friction, radiopacity, and biodurability [10]. Table 4.3 summarizes the various stent materials developed and currently in use.

Recent advances in ureteral stent materials also include biodegradable stents. A biodegradable stent would allow for ureteral drainage without the need for secondary procedures to remove the stent. The Temporary Ureteral Drainage Stent (TUDS, Boston Scientific) completely dissolved in 84% of patients after 1 month; however, stent fragments persisted for more than 3 months in three patients requiring surgical removal [11, 12]. Due to the concern about retained fragments, the TUDS is no longer available. Biodegradable stents made of L lactide, glycolide are currently awaiting clinical trials, but appear to completely dissolve after 4 weeks in animal models [13].

Metallic stents were also developed to avoid encrustation, improve urinary flow despite malignant obstruction, and allow for longer dwell times. The Memokath 051 is a titanium-nickel alloy that expands into shape at body temperature. It has a bell shaped tip that helps keep the stent in place and is designed to be placed only at the site of the obstruction with minimal stent material in the bladder or kidney [14]. The resonance metallic stent looks like a standard double J stent, but does not have an inner hollow core. Flow occurs around the coils of the stent [15]. It is made of a corrosion-resistant, MRI-compatible, nickel-cobalt-chromium-molybdenum alloy and demonstrates very high tensile strength [16].

Designs Ureteral stents come in many different shapes and designs (see Fig. 4.4a–g). The various stent designs were developed to improve the specific function of the stent and/or minimize patient reported symptoms.

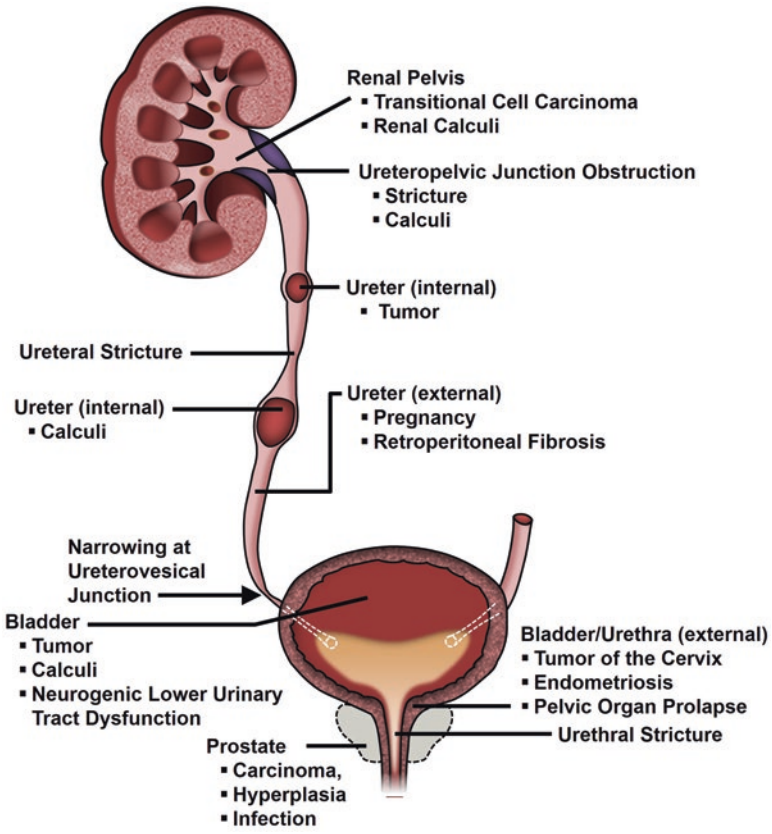

Fig. 4.2 Upper and lower urinary tract causes and sites of obstruction—Courtesy of Diane Newman

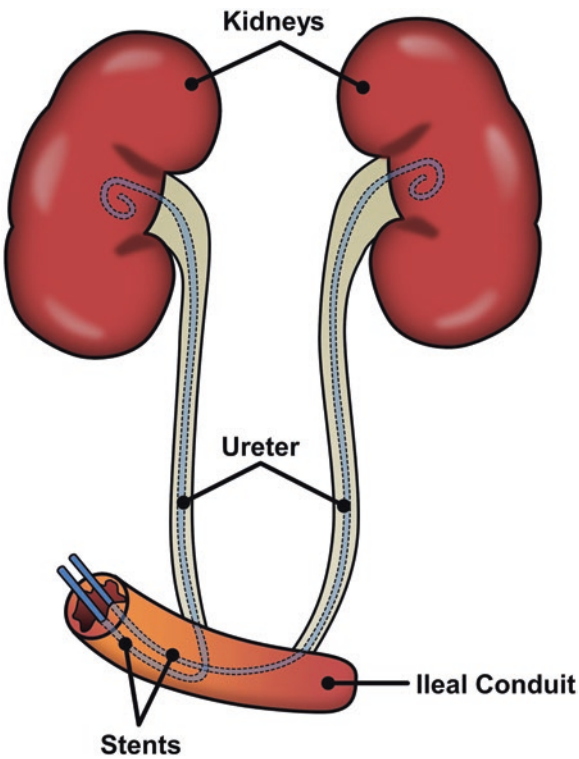

Fig. 4.3 Ureteric stents coiled in the renal pelvis to prevent moving out of place and dislodgement. Stents protrude through the ileal conduit

Table 4.3 Various ureteral stent materials and properties

	Polyethylene	Polyurethane	C-flex® (Cook Medical) silicone-modified styrene/ethylene/butylene block thermoplastic copolymer	Percuflex® (Boston Scientific) proprietary thermoplastic copolymer	Silicone
Biocompatibility	Low	Low	Intermediate-high	Intermediate-high	High
Biodurability	Low	Intermediate	Intermediate	Intermediate	Intermediate
Memory	High	High	High	High	Low
Tensile strength	High	High	High	Intermediate-high	Low
Elongation capacity	High	Intermediate	High	Intermediate	Low

Adapted from Mardis et al. [7]

The *double-J* is the most commonly used ureteral stent (see Fig. 4.4a). First introduced by Finney [4] in the late 1970s, it was designed to minimize the problems associated with stent migration. The double-J stent has pigtail coils at the proximal and distal tip of the catheter. Anchoring the proximal J-hook within the renal pelvis and the distal J-hook within the bladder keeps the stent from slipping or migrating up or down [17]. While most modern stents have pigtail coils (full coils) the term "double-J" is still commonly used to describe these stents.

Every major stent manufacturer produces a double-J stent. Double-J stents range in diameter from 4.8 French (Fr) to 10 Fr and in lengths (measured between the start of the pigtails) from 10 centimeter (cm) to 30 cm. Each stent has end-holes and multiple side-holes that allow urine to drain freely from the kidney's upper collecting system down through and around the stent, and into the bladder.

Multicoil stents allow for a single stent length for all patients (see Fig. 4.4b). Excess stent is coiled in the bladder to minimize irritation to the trigone. Multicoil stents also have similar diameters to standard double-J stents.

Grooved stents were developed to improve extraluminal stent drainage. In most cases, stent drainage occurs intraluminally (through the hollow portion of the stent) and around the stent (see Fig. 4.4c). A small groove made on the outside of the stent was designed to increase extraluminal flow.

Tail stents/Dual durometer stents are used to minimize patient discomfort by removing the coil from the bladder portion of a double-J ureteral stent (see Fig. 4.4d) [18, 19]. The proximal or renal side of a tail stent is configured like a standard double-J stent, though the bladder or distal end tapers into thin 3 Fr closed tip tails [19]. The distal portion of the stent is also occluded in order to decrease urinary reflux up the catheter with voiding. The tails are kept long to aid in easy retrieval if proximal migration occurs and the stents only come in one length [18].

The Polaris™ stent is a combination of a tail stent and dual durometer stents. Dual durometer stents are made of two different materials. Firmer biomaterials are used on the proximal or renal side, while softer biomaterials are at the bladder end. Despite these properties, patients reported only mildly improved stent-related symptoms [18, 20]. *Endopyelotomy stents* are used for upper tract drainage after incising the ureteropelvic junction (UPJ) (see Fig. 4.4e). These stents taper from a large caliber diameter (usually 10–14 Fr) to a smaller distal (bladder) diameter (7–8 Fr) (see Fig. 4.4f). In order to minimize ureteral tissue ingrowth on the stent during healing after endopyelotomy, no side drainage holes are present on the proximal or renal portion of the stent [4].

Open ended or universal catheters have no coils and are long enough to allow for external drainage (see Fig. 4.4g). These long straight hollow tubes are temporary catheters that can be used to perform retrograde pyelograms, collect urine or specimens from the upper tracts, and aid in the placement of guidewires for endourologic procedures. They are also frequently placed in the ureter prior to complex pelvic surgery in order to aid in the identification of the ureter during surgery and avoid inadvertent ureteral injury. The open-ended type catheter has an opening at the tip of the catheter. The universal or Pollock catheter has a rounded atraumatic tip with a side exit hole. This design allows for atraumatic placement in the upper tract without the need for a guidewire.

Single J ureteral stents have a single pigtail coil on the proximal or renal end, and a long straight segment. These are generally used for external drainage or drainage of the upper tract after urinary diversion surgery.

Techniques for Use

Stent placement: The standard double-J stent is usually placed during cystoscopic examination of the bladder. General anesthesia is often necessary for placement. After cystoscopic examination of the bladder, the ureteral orifice is identified. A small wire is then advanced into the orifice. Confirmation that the wire is in the appropriate position in the kidney can be accomplished with fluoroscopic or ultrasonic images. Usually an open-ended catheter is then advanced over the wire into the kidney. Contrast dye is gently injected to fill and outline the collecting system. The wire is then replaced back into the upper tract. Using fluoroscopic

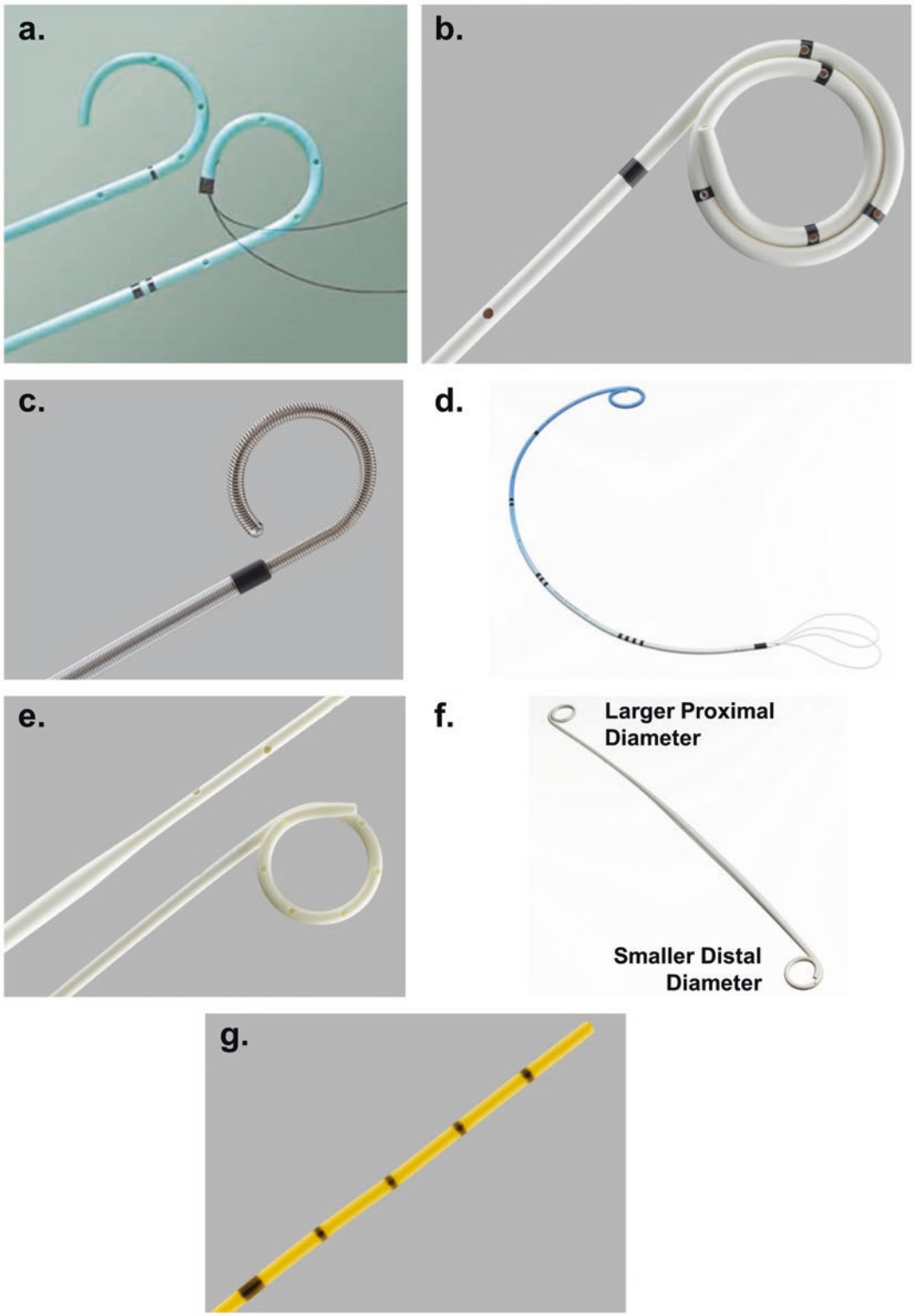

Fig. 4.4 Ureteral stent designs. (**a**) Double-J stent—there are loops at either end to keep the stent in place, distal coil with attached string. (**b**) Multicoil stent-multiple loops will form at the ends. (**c**) Grooved stents allow for extraluminal drainage (metallic Ressonace stent—Cook Medical). (**d**) Polaris Loop Ureteral stent consists of a tail for the bladder end and standard coil for the kidney. It is also composed to two different materials at the renal and bladder side. (**e**) Endopyelotomy stent with a large diameter renal side that tapers to standard size double J stent. No side hole is made in the renal side to prevent tissue ingrowth. (**f**) Endopyelotomy stent indicated by the smaller catheter size at the distal end and larger size at proximal end. (**g**) Open ended ureteral catheter. A simple tube designed to extend from the kidney to outside of the body

guidance, the ureteral stent is advanced into the appropriate location and coiled. An adequate coil can be directly visualized in the bladder through the cystoscope.

There are several alternative methods for placing ureteral stents including using only fluoroscopic guidance without direct cystoscopic visualization. This method can be performed over a guidewire or in some cases, assisted with an 8–10 Fr dilator. The 10 Fr portion of the dilator is left in position in the ureter as the stent is advanced through the 10 Fr portion. The technique allows for less buckling of the stent in the bladder as it is being advanced. Since these methods rely on fluoroscopic guidance for correct stent placement, care must be taken to avoid pushing the ureteral stent too far proximally and beyond the ureteral orifice into the distal ureter.

Stent removal: Internal ureteral stents can be removed via two methods. For patients who need a temporary stent (<1 week), a long nylon suture is tied to the distal tip of the stent. This suture—referred to as an "extraction string"—is brought out through the urethra and secured externally with tape to the penis or pubic region. During stent removal, the suture is gently pulled until the entire stent is removed. The stent is often removed in the office by an advanced practice provider (nurse practitioner or physician assistant) or the urologist. In some cases, patients may remove the stent at home. A systematic review of ureteric stents on extraction strings by Oliver and colleagues [21] found that the strings are easy for patients to self-remove and can reduce the stent dwell time for patients, resulting in less morbidity and undue burden. While this technique does not require a cystoscopic examination of the bladder to remove the stent, it should only be performed for stents that will be removed quickly (<1 week), since the external string can be prone to inadvertent stent dislodgement.

In situations where the stent is left "without a string," a cystoscopy must be performed to retrieve the stent. The stent is seen in the bladder and grasped with an alligator forceps or basket and gently removed. This is most commonly performed in the office with local anesthesia. A magnetically tipped stent was developed to make retrieval easier and to avoid a cystoscopy; however, since 20% of the stents could not successfully be removed without a cystoscopy, the product has been removed from the market [22]. Recent updates in magnetic tip design have shown promising results, and magnetic retrieval of ureteral stents may be available in the future [23, 24].

After stent removal, the patient may experience some transient discomfort or ureteral spasm. This is often mild and controlled with non-steroidal anti-inflammatory drugs (NSAIDs) or narcotics. In most cases, stent-related symptoms will resolve within a day or two after stent removal. Follow-up imaging after stent removal depends on the procedure performed and may include renal bladder ultrasounds, renal scans and cross sectional imaging with magnetic resonance imaging (MRI) or computed tomography (CT) scans.

Complications/Adverse Events/Prevention

Stent-related problems are extremely common. More than 85–90% of all patients who have an indwelling ureteral stent will report some complication after placement [25, 26]. Complications include irritative voiding symptoms (frequency, urgency, nocturia, and dysuria), flank pain, suprapubic pain, and hematuria. Joshi et al. [27] developed and validated a Ureteral Stent Symptoms Questionnaire (USSQ) to report stent-related pain, urinary symptoms, sexual dysfunction, and decreased work productivity. This tool has helped standardize knowledge of stent-related complications and allowed for validated assessments of interventions that can improve stent-related issues. The following details stent-related complications:

Stent pain/voiding symptoms: More than 80% of patients report significant stent-related pain affecting daily activities, while 78% will report irritative voiding symptoms [25, 28, 29]. Stent-related flank pain (25%) is likely due to the reflux of urine up the stent during increased intravesical pressures while voiding [30, 31]. As pressure is transmitted up the stent, intrarenal pressures rise, causing pain and discomfort in the flank. This phenomenon is sometimes called the "water hammer." Pain associated with the stent may also be related to the movement of the stent within the kidney, ureter, and/or bladder [32]. Stent removal can result in flank pain, as well as lower urinary tract symptoms (LUTS), urgency, frequency, and incontinence, due to the irritation of the bladder mucosa [33, 34].

A number of studies have looked at ways to improve stent-related pain and voiding dysfunction, which is also likely due to trigonal irritation [33, 34]. Patients with the distal coil crossing the midline of the bladder report more pain, voiding symptoms, decreased work performance, worsening sexual function, and more analgesia requirements than patients with more appropriately placed stents [35, 36]. Overall, stents that cross the bladder midline, have longer amount of time in-situ, develop urinary tract infections (UTIs), and have all been associated with patient pain and discomfort due to the caliceal position of the upper renal coils [37, 38].

Stent diameter does not appear to influence the severity of stent-related symptoms. A larger sized diameter stent does not appear to cause more symptoms of pain, hematuria, or irritative voiding complaints. A number of studies have compared various stent sizes ranging from 4.8 Fr up to 14 Fr endopyelotomy stents, and have shown that stent-related symptoms do not improve even when smaller diameter stents are used [39–41].

Various studies have also examined the effects of stent materials on urinary scores and discomfort. While many of these studies suggest that stents created from softer materials may be better tolerated, no single stent material appears to have a distinct advantage over other stents in terms of minimizing renal pain and dysuria [7, 20, 42, 43].

Despite appropriately placing and sizing the stent, patients will still experience stent-related urinary symptoms and pain. A number of medications have been studied to reduce overall stent-related symptoms. While NSAIDS and narcotics can help alleviate stent-related pain, voiding symptoms are not improved with these medications [44]. Alpha blockers are the only medications in a number of randomized controlled trials that have been shown to significantly decrease the rates of stent-related pain, LUTS and sexual dysfunction, and improve overall general health scores [45]. Both alfuzosin and tamsulosin have been extensively studied for their positive effects on stent-related discomfort, but any alpha blocker would likely be associated with a decrease in stent-related LUTS and pain [40, 45–48].

Phenazopyridine HCl (a urinary tract analgesic) and anticholinergic medications such as oxybutynin and tolterodine have not definitively shown a trend towards improving pain or LUTS associated with stents. A randomized trial of phenazopyridine versus oxybutynin ER versus a placebo showed no difference in stent-related pain or irritative voiding symptoms between the groups [49]. A second trial comparing alfuzosin and tolterodine showed improved pain and urinary frequency symptoms compared to a placebo [50]. Nocturia and urgency were also significantly improved in the tolterodine group, but overall health, sexual performance, and work performance did not differ between the groups. The combination of terazosin and tolterodine significantly improved irritative symptoms, analgesic use, quality of life (QOL), and flank pain compared to a placebo, while tolterodine monotherapy improved some voiding parameters [51]. A combination of solifenacin and tamsulosin showed some improvement in stent-related symptoms, but these trials lacked randomization and the use of a placebo [52–54, 55]. Overall, the effects of anticholinergic medications on stent-related symptoms are likely small and may only improve stent-related urgency, frequency and nocturia.

Various intravesical treatments have also been used in attempts to improve stent-related discomfort. Intravesical instillation of oxybutynin, alkalized lidocaine, ketorolac or 0.9% normal saline immediately after stent placement has shown no major difference in pain related events after installation [56]. Interestingly, injection of the local anesthetic ropivacaine in the ureteral orifice after stent placement did not improve LUTS or stent-related pain; however, a small dose of onabotulinumtoxinA (BTX) injected in three sites around the ureteral orifice did improve postoperative pain and decreased analgesia use [57, 58]. Symptom reductions were noted immediately after the injection, suggesting that BTX may have some immediate analgesia effects in the bladder and ureter. However, most of these studies suffer from the lack of placebo use and small sample sizes. Further research is needed to see if intravesical therapies are beneficial.

Best Practice Management for Adverse Events

Stent pain and lower urinary tract symptoms (LUTS) are common and often unavoidable. In order to minimize some of these effects, the stent should be sized appropriately so that it does not cross the midline of the bladder and should be placed in the renal pelvis. Small diameter stents, as well as specialty stents (floppy tail, etc.) may only slightly improve some of these symptoms. As previously stated, alpha-blockers do appear to be effective in reducing some symptoms and should be considered if appropriate after stent placement. Anticholinergic medications may improve irritative voiding symptoms, but are not effective in managing stent-related pain. Phenazopyridine and other intravesical or intraureteral agents may also provide some benefit, but the data supporting their use is limited.

Sexual dysfunction associated with an indwelling ureteral stent is also a common, if under-reported or under-recognized, issue found in 32–86% of patients with an indwelling stent [59]. Females are more likely to report sexual dysfunction due to the distress of having a foreign body in the bladder [60]. The International Index of Erectile Function and the Female Sexual Function Index decline significantly following stent placement. Similar to stent-related pain and voiding dysfunction, alfuzosin appears to significantly reduce pain with sexual intercourse and improve overall satisfaction with sexual activity in both men and women [46].

Hematuria or gross hematuria, immediately after stent placement is also common and usually self-limiting, while microscopic hematuria may be present while the stent remains in place. Hematuria may be a sign of a UTI or anticoagulation therapy. Ureteroarterial fistula is an extremely uncommon but severe complication of ureteral stenting. It often presents with intermittent gross hematuria and massive hemorrhage during stent exchange. Predisposing factors for fistula formation include having an indwelling stent for >1 year (even with routine changes), previous pelvic surgery, radiation therapy, and underlying vascular disease [61]. Treatment includes embolization, vascular stenting, or open repair [61, 62].

Stent-related urinary tract infections are reported in 20–30% of patients after stent placement, and will often

occur despite the use of prophylactic antibiotics [63–66]. They are difficult to diagnose because of the similarities between symptoms of routine stent discomfort and UTIs [64]. The biggest risk factor for the development of bacteriuria and colonization of the ureteral stent is dwell time, with bacteria rates of <20% in most series at 1 month rising to >40% after 3 months [64, 66–68]. Rates of colonization were much higher than bacteriuria and also increased precipitously with longer dwell times. No colonization was found with dwell times less than two weeks [68]. Thus, it would be prudent to change stents more frequently in patients who are having recurrent UTIs.

Infections and bacterial colonization are caused by the formation of biofilms and encrustation on the stent [69, 70]. These processes provide bacteria with an environment protected from antibiotics [70]. Dwell time, a history of diabetes, female gender, chronic renal failure, and pregnancy were also risk factors for the development of bacteria and colonization [68, 71]. The most frequent organisms associated with stent-related infection include enterococcus, *Staphylococcus aureus*, pseudomonas, and *Escherichia coli* [72]. Treatment should be tailored to the individual organism; however, in some cases the stent may be colonized with a completely different organism [63]. If a stent becomes severely encrusted, it can lose flexibility and may be more prone to fracture. Removal or replacement of the stent is necessary if the infection cannot be cleared with antibiotics or if the dwell times are long.

While there are no currently available methods or materials that avoid biofilm formation and encrustation, early stent removal and use of prophylactic antibiotics can help reduce the risk of infections in patients who are at high risk for infection or encrustation. In general, however, antibiotics should not be used prophylactically for all patients [73]. Patients with diabetes, chronic renal failure, and pregnancy should be monitored closely and scheduled for shorter stent dwell times or removal. Overall, the most successful method to reduce stent-related infection is removal of the stent as early as possible.

Stent Encrustation and the Forgotten Stent

Stent encrustation is one of the most complicated challenges of ureteral stents. Encrustation occurs as a result of the development of biofilms on a stent's surface. Biofilms consisting of albumin, Tamm–Horsfall proteins and various other urinary proteins can cover the stent surface almost immediately after stent placement [70, 74, 75]. These films support the aggregation and precipitation of various magnesium or calcium based crystals. Bacteria can also become trapped in the biofilm leading to further crystallization, encrustation, and potentially to symptomatic UTIs that are difficult to treat because of the protective nature of the biofilm [70]. Encrustation can occur on the outside and intraluminal cavity of the stent, leading to stent failure and obstruction.

Longer dwell times are the biggest risk factor for stent encrustation [76]. After six weeks, 9.2% of stents are encrusted, compared to 76.3% of stents at twelve weeks. Other risk factors include a history of urolithiasis, chemotherapy, bacteriuria or infection, and pregnancy [76]. In these patients, stents should be closely monitored and changed frequently. Overall, standard stent material should be removed or replaced every 2–4 months, depending on an individual patient's tendency towards encrustation.

Managing the "forgotten" severely encrusted stent can be extremely challenging. Often the stone burden on the stent is massive, covering both the proximal and distal curls of the stent as well as, the entire ureteral length. Various methods for removing such stents have been employed, including shock wave lithotripsy, ureteroscopy and combined ureteroscopy, and percutaneous approaches [76–80]. Often multiple procedures are required to remove the entire stent and stone burden. Increased dwell time in the ureter can also lead to stent degradation and brittleness which in turn leads to stent fracturing and increases the complexity and difficulty of extraction. In some rare cases, patients will present with a fractured stent [81].

The best method to prevent stent encrustation and the complex procedure needed to remove a forgotten stent is to simply avoid the complication. This can be achieved by close patient monitoring after stent placement. Some programs employ computerized tracking and retrieval systems that notify the physician when a stent is overdue or needs to be removed [82]. These systems have resulted in significant declines in the percentage of forgotten stents.

Stent Failure

Stent failure can be a major complication of an indwelling ureteral stent. Stent failure can occur in the absence of stent encrustation and in patients with intrinsic or extrinsic obstruction [83]. While most cases of intrinsic obstruction can be successfully managed with stent replacement or definitive repair of the underlying problem, extrinsic or malignant obstruction is more commonly associated with stent failure [84, 85]. Patients with malignant causes for obstruction should be closely monitored for worsening hydronephrosis since worsening pain may be related to the underlying disease process and changes in serum creatinine may be misleading if the patient has a normal contralateral kidney. Renal ultrasounds or other cross section imaging to

assess for hydronephrosis and periodic routine stent changes can help avoid the risk of permanent renal injury [86, 87]. If a stent fails due to extrinsic malignant obstruction, management options include increasing the diameter of the stent, placing two parallel stents, using metal stents or placing a percutaneous nephrostomy tube [86, 88–90].

Stent Migration

Since the introduction of the double-J stent in the early 1970s, stent migration has become an uncommon problem, with a reported incidence of less than 2–8% [91, 92]. Stent migration that occurs distally is easily managed by replacing the stent. Proximal stent migration is less common with an incidence of 1–4%, but more difficult to manage [92]. Risk factors for proximal stent migration include smaller diameter stents (4.8 Fr stents are more likely to migrate or dislodge compared to 6 Fr stents) [41], dwell time, shorter length, inadequate curl or improper stent positioning [91–93].

Proximal stent migration can be managed by ureteroscopic retrieval with either a stone basket, alligator forceps or three-pronged graspers. An alternative retrieval method entails placing ureteral dilating balloons next to the stent or within the lumen of the stent, and slightly inflating the balloon to increase friction and pull the stent down [94–96].

Percutaneous Nephrostomy Tube

Definition

Percutaneous nephrostomy (PCN) tubes are external drainage tubes placed directly into the kidney (See Fig. 4.5a, b). The most common site to place a PCN tube lies approximately 1 cm below the tip of the 12th rib and 1 cm medially. This site provides for easy access to the lower pole of the kidney and avoids injury to the colon, liver, and spleen (see Fig. 4.6). A PCN tube allows for external drainage of the kidney, bypassing the ureter and bladder. One of the first uses of percutaneously placed tubes in the kidney was described by Goodwin et al. in 1955 [97, 98]. Since then a large number of tube designs and uses have been developed.

Indications

The indications to place a PCN are similar to a ureteral stent (see Table 4.2). One of the most common indications is to establish upper tract drainage after failed placement of a ureteral stent. Since the placement of a PCN can be completed with local or minimal anesthesia, it is sometimes utilized as the primary therapy in patients at high anesthetic risk.

Some urologists will place a PCN tube prior to endourologic procedures in the kidney such as percutaneous nephro-

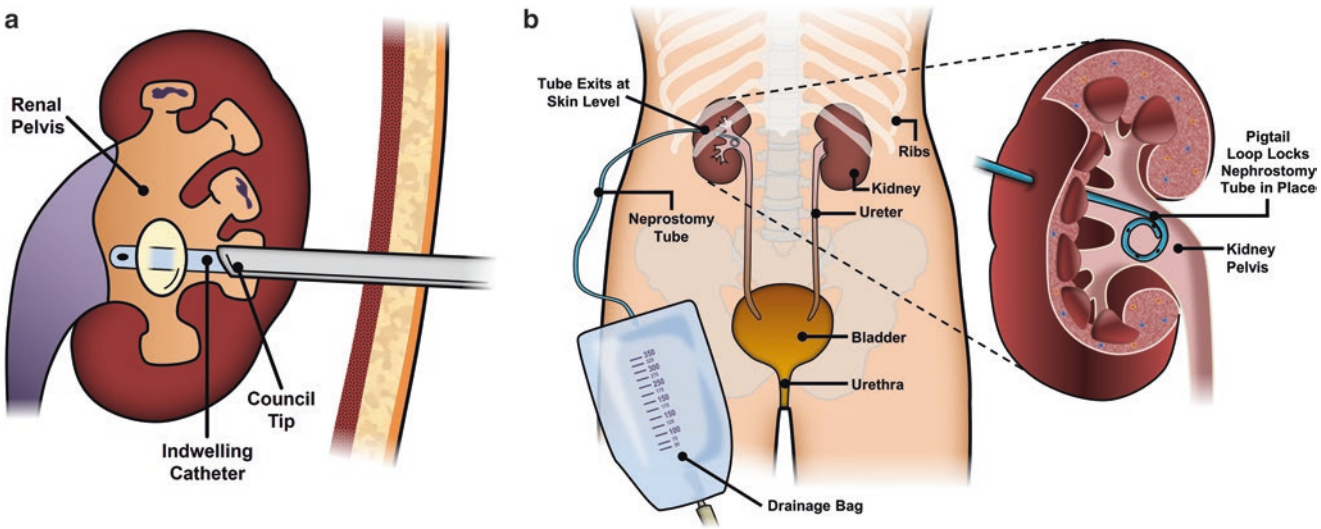

Fig. 4.5 (**a**) PCN tube being passed into the kidney pelvis through a council tip catheter. (**b**) PCN tube in place, attached to a drainage bag

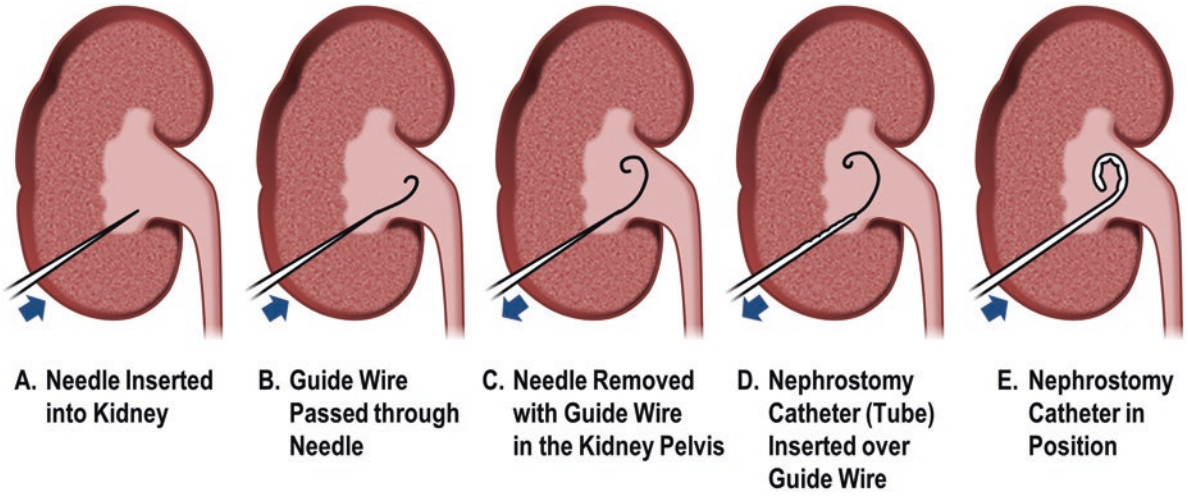

Fig. 4.6 How a PCN tube is placed into the kidney

lithotomy (PCNL), endopyelotomy, or foreign body retrieval (fractured stent). In this situation, the PCN tube allows for hemostasis, future renal access, if necessary, and/or the administration of medications directly into the kidney.

Materials

Nephrostomy tube biomaterials are often made from the same materials used for ureteral stents (see Table 4.3) and urethral or indwelling urinary (Foley) catheters (IUC). These materials include: polyurethane, polyethylene, silicone, silastic, C-flex™, Percuflex™ and latex. Nephrostomy tubes can either be attached to a drainage bag for continuous urine drainage (see Fig. 4.7), or the tube can be capped (if adequate antegrade drainage is assured) as seen in Fig. 4.8. Drainage bags are discussed in Chap. 5.

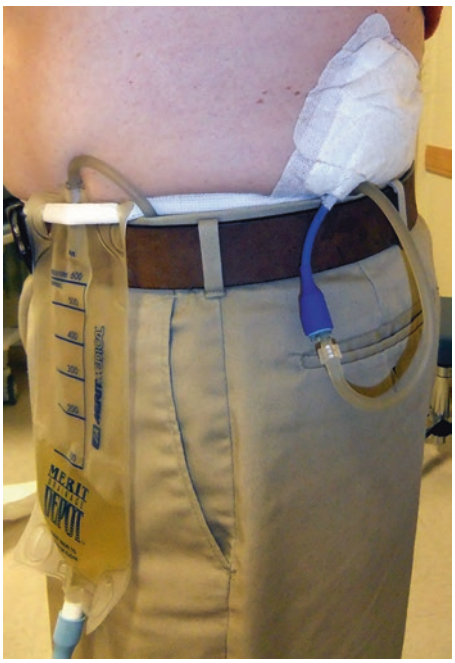

Fig. 4.7 PCN tube attached to a drainage bag for continuous urine drainage

Designs

A number of designs for PCN tubes exist (see Fig. 4.9a–d). Tube diameters range from 5 Fr to 32 Fr for a broad array of clinical applications. Designs include a standard retention balloon catheter (e.g., IUC), Council tip catheters, Malecot catheters, Cope Loops (pigtail catheters), pezzer or mushroom catheters (used for suprapubic catheter), Circle tubes, Kaye Tamponade catheters, re-entry tubes, and nephroureteral stents. The clinical purpose for the tube should dictate the design chosen. Table 4.4 summarizes the various nephrostomy tubes.

Pigtail catheters (Cope Loops) or single J type catheters are the smallest PCN tubes available (see Fig. 4.9a). They range in size from 5–14 Fr. They are designed to allow for simple drainage of the kidney, with small diameter holes spaced along the pigtail coil to allow for drainage. Similar to pigtail ureteral catheters, the pigtail coil reduces the risk of migration or dislodgement. The Cope loop has a nylon suture attached to the tip of the catheter that helps maintain the pigtail shape and the position of the catheter in the kidney regardless of tension or movements by the patient.

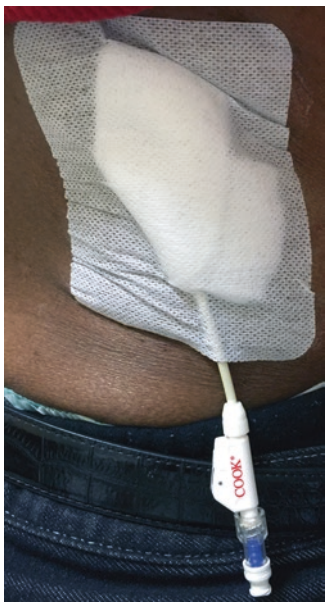

Fig. 4.8 PCN tube capped and with dressing

Balloon catheters and balloon retention catheters include the IUC and Council tip catheter (see Chap. 1). These catheters come in sizes from 12–32 Fr (16 Fr for Council tip catheters). Once the catheter is placed into the collecting system, the balloon is slightly inflated to maintain the position of the tube in the kidney. The diameter of these tubes is much larger and the drainage eyelets are less likely to clog due to the much larger size compared to the pigtail catheter. Thus, they are ideal for maximal urinary drainage or for draining blood or thick purulent materials.

Malecot catheters are very similar to balloon retention catheters, except a small mushroom shaped tip replaces the balloon (see Fig. 4.9b). Malecot catheters come in sizes from 8–24 Fr; however, when compared to balloon catheters, smaller-diameter Malecot tubes provide a greater inner diameter for drainage, because there is no balloon port. Malecot catheters may also cause less calyceal obstruction, compared to balloon catheters, due to the mushroom shaped tip. Malecot catheters, however, are more likely to become

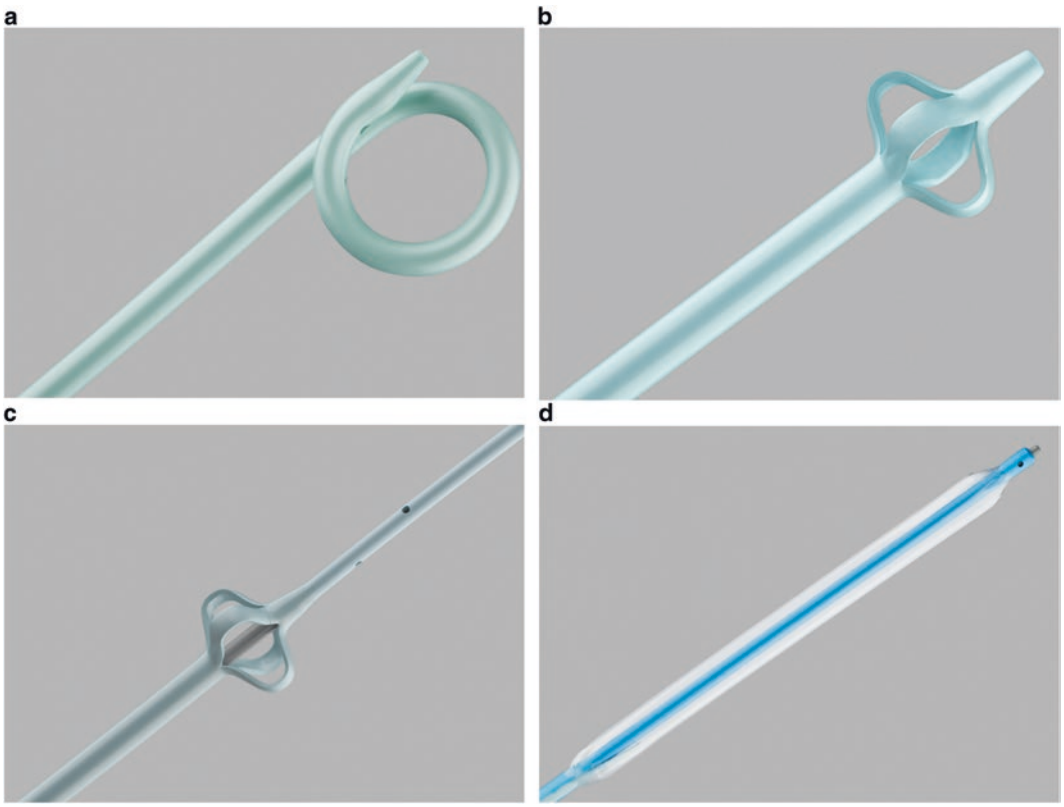

Fig. 4.9 (**a**) Pigtail catheter—the loop is designed to prevent dislodgement. (**b**) Malecot catheter—the mushroom tip is the retention mechanism. (**c**) Malecot Reentry catheter—note the narrow tip designed to extend down the ureter. (**d**) Kaye Tamponade Catheter—the balloon at the tip is designed to stop bleeding

Table 4.4 Types of nephrostomy tubes

Type	Description	Indications
Cope loop NT	• 5–14 Fr • Narrow-bore tubes with self-retaining mechanism by the use of a string that exits the catheter a few centimeters from the distal tip and then re-enters the catheter near the tip • Pulling on the string forms a secure coil that is not easily dislodged • Same coil shape as a pigtail stent	• Simple upper urinary track drainage and instillation procedures • May be used post PCNL in adults • Used in routine or problematic PCNL in children
Council tip catheter	• 12–24 Fr • Self-retaining with a balloon • Easy to insert and exchange over a guidewire • Can create a Council tip by cutting the end of the tip of an IUC and threading a wire through the tip	• Larger diameter allows for drainage of urine that may be mixed with blood, mucus or stone debris, and may provide tamponade of renal hemorrhage • Balloon has the potential to occlude one or more calyces and may be a source of discomfort to the patient; thus, avoid over-inflation of the balloon
Malecot catheter	• 8–24 Fr • Self-retaining mushroom-style tip (either two or four wings on one end that can expand) • Typically fixed to the skin with nonabsorbable suture	• Avoids use of a balloon • Provide temporary permanent diversion of urine after kidney surgery when renal tissue needs to be restored • May also be used for suprapubic drainage • Commonly used post PCNL
Re-entry PCN	• 8–24 Fr in their proximal segments • Extending from the Malecot portion of the catheter is a 17 cm or 18-cm extension of 5–8 Fr, which is advanced into the ureter, preserving ureteric access should it become necessary	• Provide large-bore drainage after PCNL • Can be reinserted if serious bleeding is recognized during tube removal • Provide effective UPJ stenting
Circle NT	• 12–22 Fr • Needs two access tracts, enters the kidney through one calyx and exits via another • Easy to insert • Secure • Cost effective compared to inserting two Cope loop tubes	• Facilitate easy drainage of even the smallest renal pelvis • Requires less frequent changes as multiple side holes and silicone design help resist encrustation and infection. • External drainage requires a *Y*-connection

Courtesy of Diane K. Newman; Bailey L & Jaffe WI. Obstructive uropathy. In DK Newman, JF Wyman, VW Welch (Eds). Core Curriculum for Urologic Nursing (1st ed., p. 409, 2017), Pitman, NJ: Society of Urologic Nurses and Associates, Inc.

dislodged, because of the floppiness of the tips as compared to locking pigtail catheters or balloon catheters.

Re-entry catheters allow for easy access back into the kidney if needed for repeat procedures or bleeding. The most common type of re-entry catheter is the Smith reentry catheter. These catheters come in sizes from 8 Fr to 24 Fr and are Malecot catheters with a long 18 cm 5–8 Fr extension that can be placed down the ureter (see Fig. 4.9c).

Kay Tamponade catheters are specialized PCN tubes that are used as a method to control bleeding after PCNL. The catheter has a balloon that is much longer than a typical balloon catheter and can be inflated to tamponade bleeding from the renal parenchyma after surgery. A large inner diameter also provides renal drainage (see Fig. 4.9d).

Nephroureteral stents are designed to be placed percutaneously, but transverse the entire length of the ureter and coil in the bladder. Similar to a double-J stent, nephroureteral stents have two pigtail coils. One coil is placed into the bladder, while the second is coiled into the renal pelvis or within a calyx. The tube then exits the body and drains into an external collection bag. These tubes can also be capped to allow for internal drainage into the bladder.

Circle Tubes (u Loops) are rarely used today and require two separate access points in the kidney. The tube enters one calyx and exits a second calyx providing a continuous loop for drainage.

Complications

Overall, PCN tube placement has a reported success rate >98% [99, 100]. Most of the complications associated with PCNs are due to tube placement. The rate of complications from PCN tube placement is estimated at 8–10% [101–103]. While most patients with a simple PCN tube will not report voiding issues, if a nephroureteral stent is placed, a patient may experience all of the same problems associated with a double-J ureteral stent described previously. Since PCN tubes are made from the same materials as ureteral stents and urethral catheters, they are also prone to all of the effects of biofilms, encrustation and infections. Unique complications due to PCN tube placement are described here.

Hematuria: Hematuria and mild bleeding after PCN placement is not uncommon; however, major hemorrhage

that requires transfusion or close monitoring occurs in 1–3% of patients [102]. This is likely due to injury of the large segmental arteries in the kidney. Most bleeding complications resolve spontaneously without intervention or with clamping of the nephrostomy tube; however, in some cases embolization is necessary [102, 104]. Use of indwelling nephrostomy tubes with a balloon after PCNL can reduce blood loss [105].

Other complications: Sepsis can also be a serious complication, but the rates of sepsis are generally less than 2% [22, 104, 106]. Other complications due to tube placement include pulmonary injury (pneumothorax, hydrothorax), which is more common with upper pole access. Injury to surrounding organs such as the spleen, liver, and bowel is also possible. Minor complications such as perforation of the collecting system, blockage or dislodgement are more frequent and easily managed by replacing or repositioning the tube in the appropriate location [107]. The PCN tube can also become clogged or occluded. Gently flushing the tube with 10 mL of sterile saline daily can prevent tube occlusion.

Prevention of Nephrostomy-Related Adverse Events

Methods to prevent PCN-related adverse events are similar to methods described previously regarding ureteral stents. Caring for the tube and site of insertion is also important. Making sure not to dislodge the tube, and keeping the area clean and dry will reduce PCN failure and infections. Flushing the tube with sterile saline may also prevent tube occlusion or failure.

Evidence Based Practice Management for Stents and Nephrostomy Tubes

Despite widespread use of ureteral stents and nephrostomy tubes, evidence-based practice management data for many of their uses has only recently become available. Many earlier studies lack consistent or validated questionnaires or were poorly powered to show differences in therapy.

Stent After Ureteroscopy

Recent changes to Medicare coding now bundle the placement of a double-J stent with ureteroscopy. This underscores the widespread practice of placing a ureteral stent after ureteroscopy. However, a number of prospective randomized trials in patients undergoing uncomplicated ureteroscopic stone removal have shown that there were no differences in complication rates between the stented and non-stented groups without any impact on stone free rates [28, 107–111]. Patients who did receive a stent had significantly more LUTS, dysuria, flank and abdominal pain, and hematuria [111]. Nor were unplanned hospitalizations different between the stented and unstented groups; however costs (due to office visits or procedures for stent removal) were much higher for the stented population [112]. Predictors of poorer outcomes in patients with uncomplicated ureteroscopy performed without a stent included procedure length greater than 45 min, larger stone burden, history of nephrolithiasis, and infection [6, 111]. Therefore, in most uncomplicated procedures, with small stone burdens, ureteral stent placement does not appear necessary.

Ureteral Stent Versus Percutaneous Nephrostomy Tubes for Hydronephrosis and Obstruction

A few randomized trials have been performed that compare ureteral stents to PCN tubes for the management of hydronephrosis due to obstruction with or without infection. Overall, a PCN tube showed greater success in relieving obstruction without infection (100% versus 80% in the ureteral stent group) [112]. Less radiation exposure was also noted in the percutaneous group and QOL measures improved in the percutaneous group while declining in the stented group [113].

In the setting of an acutely obstructing stone with evidence of infection, Pearle et al. [114] randomized patients to immediate ureteral stent versus PCN. No differences were found in the two treatment modalities. Due to the morbidity associated with delaying treatment for an infected renal unit, the optimal route likely depends on the availability and speed of decompression rather than the method [115].

Pregnancy

Patients with urinary obstruction, due to stones during pregnancy, pose a very difficult challenge. Limitations in use of radiation and physiologic ureteral dilation makes diagnosis of potentially obstructing stones difficult. Since 60–80% of stones will pass spontaneously in pregnancy, conservative management is often successful [116–118]. However, surgical treatment is indicated if there is intractable pain, evidence of infection or sepsis, obstruction of a solitary kidney, bilateral obstruction, or obstetric complications [117–119].

Ureteral stents and PCN tubes are both acceptable options to relieve obstruction in pregnant patients. There is no clear advantage to one device over the other for the management of obstructions, but small differences do exist [117–119]. In each case, the device should be placed under minimal fluoroscopic images or using ultrasound guidance. Tube changes should also be frequently performed due to the rapid encrustation of these devices [120]. Stents or PCNs should be changed every 4–6 weeks to minimize encrustations. The most appropriate device can be selected based on patient preferences, but in general, patients in the early trimesters

may do better with a PCN tube, due to the frequent changes needed and the ability to change the device with local anesthesia and under ultrasound guidance [117, 118, 121].

Best Practice Management

Placement of a ureteral stent or PCN tube is one of the most common procedures urologists perform. As with any device or procedure, stent or tube placement carries certain risks and complications for the patients. Having a deep understanding of each device and the associated risks will help the urologist and support staff (e.g. nurses) avoid and manage complications effectively. In order to manage the devices appropriately, the urologist must have a clear indication for placing the ureteral stent or PCN tube, monitor the patient closely; provide appropriate perioperative and post-operative antibiotics, and change or remove the device when necessary.

For indwelling ureteral stents, the use of medications such as alpha blockers and antimuscarinics, when possible, can help alleviate some of the potential discomfort associated with stents. Maintaining appropriate fluid intake is also good practice management for maintaining renal function. Long-term prophylactic suppressive antibiotics are not recommended in most patients. Removing the stent as quickly as possible and when safely indicated are the best options for reducing morbidity.

Percutaneous nephrostomy tubes externally drain, but, suppressive antibiotics are not recommended for most patients. If the tube stops draining, flush the tube and check for kinks. Changing the dressing around the tube when wet or after showering helps reduce local skin infections. Overall, identifying problems quickly and setting expectations for care can improve compliance with treatment and reduce the risk of adverse outcomes.

Urethral Stents and Dilators

Urethral Stents

Urethral stents are infrequently encountered or used. The most common urethral stent was the Urolume. It was a cylindrical stainless steel weave that could be deployed proximal to the external sphincter. This device was later removed from the market secondary to its high failure rate, which frequently required complicated endoscopic removal. A systematic review found that 84% of patients who were initially catheter dependent were able to urinate spontaneously after the procedure; however, 16% of implants failed at one year and 27% failed at five years [122].

Since the discontinuation of the Urolume, no permanent prostatic stents have been available in the US. The "Spanner" stent is a currently available temporary prostatic urethral stent (see Fig. 4.10). This device is a silicone tube that transverses the prostatic urethra. There is a balloon on the proximal end that is inflated in the bladder. On the distal end,

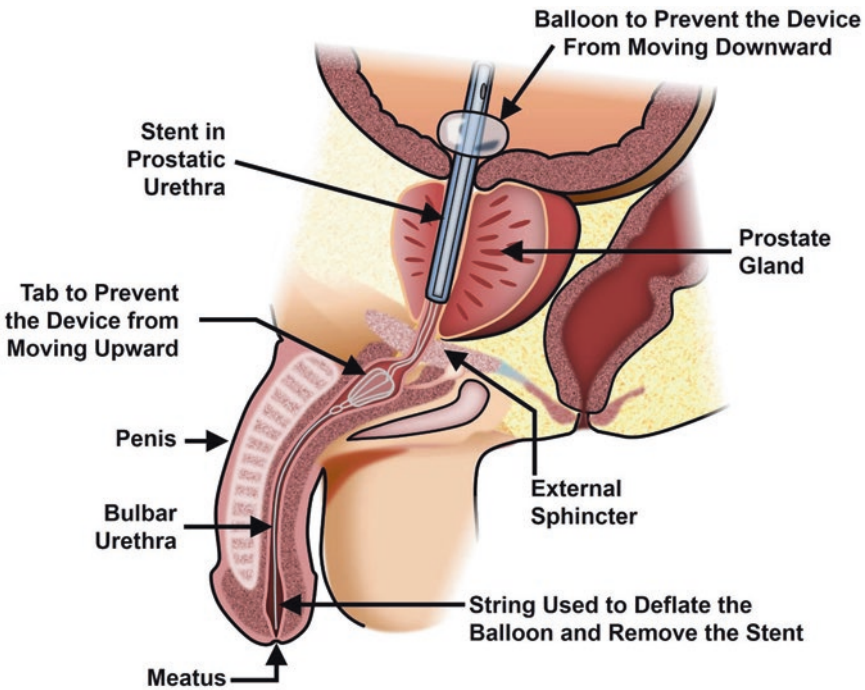

Fig. 4.10 This device (Spanner®) consists of two anchors and a silicone tube that reduces resistance in the bladder neck and prostatic urethra without stenting the external sphincter—Courtesy of SRS Medical

a plastic anchor lies distal to the external sphincter. This device has primarily been studied and used after transurethral microwave therapy and transurethral needle ablation. The largest trial of this device randomized 186 patients to either a traditional IUC or a Spanner stent following a transurethral microwave thermotherapy procedure, which is a minimally invasive surgical treatment for benign prostate disease [123]. The study found improvements in voiding and QOL parameters with the stent in place, but no difference after stent removal. The use of this urethral stent as a primary treatment for bladder outlet obstruction has been more limited. One study of the device in 42 patients found that the early removal rate was 63% secondary to nocturia, dysuria, urinary retention, or patients preferring traditional catheters [124].

Urethral Dilators

Urethral catheterization can be difficult due to various conditions including urethral stricture, meatal stenosis, false passage from previous trauma, or prostatic or bladder neck obstruction. Urethral dilators are used to stretch or dilate the urethra or meatus and allow the placement of an IUC. Table 4.5 summarizes the various urethral dilators. Urethral sounds are usually metal dilators that come in sizes from 6 Fr to 30 Fr. The sounds can be used to gradually dilate the urethral stricture under local or general anesthesia. Sounds often do not have a hollow inner core, so dilation cannot be performed over the wire and is instead done "blindly." However, some types of metal sounds, such as Goodwin sounds, can be placed over a wire and used to dilate a tightly strictured urethra.

Filiforms and followers are also used to dilate urethral strictures. These devices are indicated for IUC placement when a false passage or urethral stricture is present and prior attempts to pass an IUC are unsuccessful. Filiforms come in various shapes (straight, coiled, Coudé) and sizes 2–6 Fr (see Fig. 4.11). They are placed into the urethra and navigated "by feel" past the stricture (see Fig. 4.12). Once past the stricture, the followers are attached and used to gradually dilate the narrowing. Followers range in sizes from 6 Fr to 24 Fr. Filiforms and followers are often made from woven fiberglass material. Blind insertion of the filiforms and followers is generally reserved for when cystoscopy is not available. Since it is a "blind" procedure, a recent survey noted that less than 10% of urology residents in the US would use filiforms and followers if they failed on their initial attempt to place a

Table 4.5 Urethral dilators

Device	Description	Application	Complications	Considerations
Filiforms, followers, dilators, sounds	• Metal or plastic dilators	• Used to stretch or dilate a urethral stricture using instrumentation • Dilation of a stricture can be performed using a balloon dilator with a guidewire under cystoscopy	• Hematuria • False passage • Bladder perforation and rectal injury can occur but are rare	• Warn patients that some blood in the urine is common • Medication (opioids) for post-op pain is usually not required after first post-op day • Catheterization is common for several days to a week
Meatal dilator	• Graduated dilator	• Can be done under local or general anesthesia depending on patient • Temporary catheterization may be necessary	• False passage • Infection • Bleeding	• First dilation may be performed in office under local anesthesia or as an outpatient with general anesthesia • Counsel patient on proper technique and goals of dilation • Frequent non-aggressive episodes of dilation are favored over periodic forceful episodes
Self-catheterization (see Chap. 2)	• Catheterization with a soft 14–16 Fr catheter • In men, a Coudé tip catheter is preferred	• Catheterization is performed at home once or twice a day for a week after the initial dilation and then in decreasing intervals over time	• Infection • Compliance long-term is poor	• Office instruction on self-catheterization and assessment of patient's understanding is very important to ensure compliance • Schedule follow-up visit for 1 week to assess catheterization technique and compliance • Patient motivation is an important indicator of success of self-catheterization

Courtesy of Diane K. Newman; Bailey L & Jaffe WI. Obstructive uropathy. In DK Newman, JF Wyman, VW Welch (Eds). Core Curriculum for Urologic Nursing (1st ed., p. 410, 2017), Pitman, NJ: Society of Urologic Nurses and Associates, Inc.

Fig. 4.11 Filiform and followers. Filiforms are placed into the urethra and navigated by feel past the area of narrowing. They are then attached to dilators which are passed into the urethra and used to dilate the narrowing

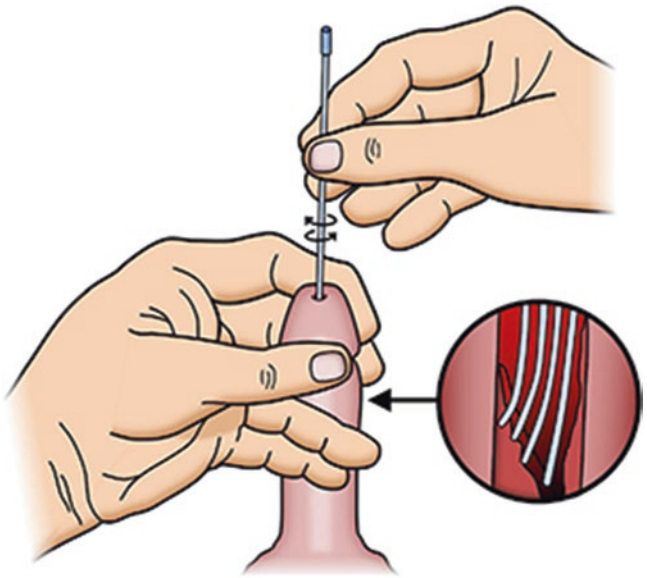

Fig. 4.12 Filiform insertion—Courtesy of Cook Medical

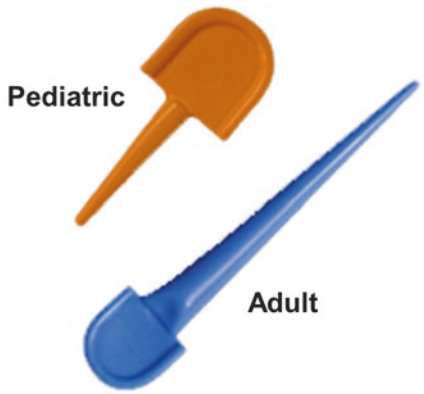

Fig. 4.13 Meatal dilators—Courtesy of Cook Medical

UC (with up to 74% instead opting to use flexible cystoscopy) [125].

The most common method to dilate a urethral stricture is with direct cystoscopic visualization of the stricture and placement of a wire into the bladder. Graduated hollow plastic dilators ranging in sizes from 6 Fr to 30 Fr can then be placed over the wire into the bladder. A Council tip IUC can also be placed in the bladder over the wire. Alternatively, a balloon dilator can be used to dilate the stricture. After a wire is placed into the bladder, a balloon dilator is then passed over the wire with the balloon portion traversing the stricture using either fluoroscopic guidance or direct visualization with a cystoscope. The balloon is then inflated dilating the stricture. Proponents of this method claim that the radial force of the balloon may disrupt the urethra less, causing less promulgation of the scar [126].

Meatal Dilators

Meatal dilators are used to dilate meatal stenosis strictures at the end of the urethra or in the fossa navicularis. These graduated dilators are often made of firm plastic. The tip of the dilator is placed in the urethra under local or general anesthesia and the narrowing is dilated (see Fig. 4.13).

Complications of Urethral Dilators

The most common complication of urethral dilation is stricture recurrence. Most patients will experience mild urethral bleeding and pain after dilation. Other complications can include UTI, hemorrhage, creation of a false passage and very rarely, rectal perforation.

Patient Information

- *Ureteral Stent Patient Education Tool*
- *Care of a Nephrostomy Tube Patient Education Tool*
- *Performing Meatal Dilation Patient Education Tool*

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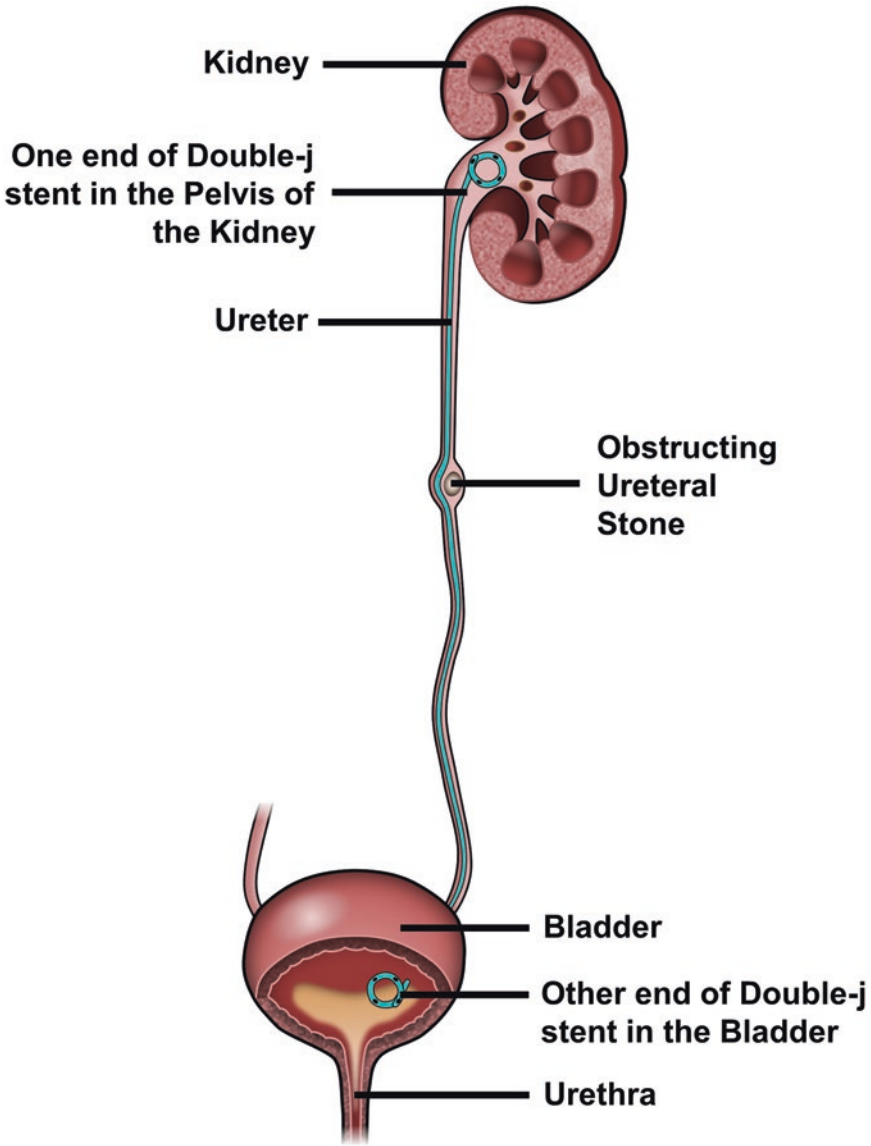
Ureteral Stent Patient Education Tool

The urinary system has several parts, two kidneys, two ureters, one bladder and one urethra. The kidneys sit at the back of the body, one on each side, just underneath the ribcage. They filter waste products from the blood into urine. Urine produced in the kidneys flows down a small tube called the ureter and into the bladder. When a person passes urine, it leaves the bladder through a tube called the urethra. Blockages can occur at the junction of the kidney and the ureter. You may have blockages around your left kidney (seen in this picture), right kidney or on both sides



What Is a Ureteral Stent?

A ureteral stent (also called a Double-J) is a hollow tube that is placed in the ureter and allows for urine to go around the place where the ureter is blocked. A stent is a short-term way to allow for drainage of a blocked kidney. This picture shows a ureteral stent (blue color) in the left kidney and ureter. This stent is held in place by coils at both ends. The top end coils in your kidney and the lower end coils inside your bladder. These coils prevent the stent from slipping up and down. A ureteral stent is in the body, so it is not seen on the outside.

How Is a Ureteral Stent Placed?

Ureteral stents are placed under anesthesia so you will be asleep. Your urologist will use a small camera and cystoscope (type of telescope), to look inside your bladder through your urethra. Once the telescope is in the bladder, the small hole where your ureter drains urine from your kidney can be seen. A wire is placed in the hole and followed on an X-ray till it reaches your kidney. A ureteral stent is then put over the wire until it is in the correct position in the kidney and bladder.

How Long Does the Ureteral Stent Stay In?

A ureteral stent is not permanent! It must be removed or it can become crusted with proteins that cause stones. In most cases, a stent will stay in place for a few days or weeks, depending on the reason for the stent. Ureteral stents should be removed or replaced after 2 to 4 months.

How Is a Stent Removed?

In some cases, a small string will be left on the stent, which will stay outside of the body. If there is a string coming from your urethra, the stent is removed by having the doctor or nurse simply pull the string. For stents that need to stay in the bladder and kidney longer, the string usually will be left on the stent. In this case, the doctor must remove the stent by looking into the bladder with a cystoscope. The stent can then be grabbed with special tools and removed. This is usually performed in the doctor's office and you will receive anesthesia but remain awake.

Are There Alternatives to a Stent?

The only alternative to astent is a nephrostomy tube. Nephrostomy tubes are inserted directly into the kidney. They are external outside the body and need a drainage tube and bag. This tube requires an external collection bag and special care.

Are There Side Effects of Having a Ureteral Stent?

Stents can cause a number of side effects. Most of these problems are minor, but can impact your daily activities.

- Bladder: You may experience pain or burning when you urinate. You also may feel some bladder urgency or sense that your bladder is not empty. Try to urinate regularly throughout the day, so your bladder does not get full, as this may cause bladder spams or cause the urine to backup into the kidney.
- Pain: A ureteral stent can cause pain in the bladder region or in your back or side near the kidney. Pain may get worse when your try to urinate. You may experience pain in your pelvic area and urethra as well.
- Sexual: While there are no restrictions to sexual activity with a ureteral stent, you may experience some discomfort during intercourse.
- Infections: Having a ureteral stent can increase your risk of developing a urinary tract infection.

Are There Any Restrictions with the Stent?

There are no limitations to your daily activities while the stent is in place. But you may experience more pain or problems the more active you are.

Helpful Tips

- Drink between *six* and *eight*—8-oz drinks or a total of 48–64 oz of liquid every day.
- If you feel that you have a fever, take your temperature. If your temperature is higher than 100.5°F, call your doctor or nurse.
- If you have a stent with a string coming from the urethra to the outside of the body, try not to pull or tug on the string. This can dislodge the stent.

When Should I Call for Help?

- If you experience a constant and unbearable pain associated with the stent.
- If you have symptoms of a bladder or kidney infection, such as fever, chills, worsening pain during passing urine, and feeling unwell.
- If the stent gets dislodged or falls out.
- If you notice a significant change in the amount of blood in your urine.

Care of a Nephrostomy Tube Patient Education Tool

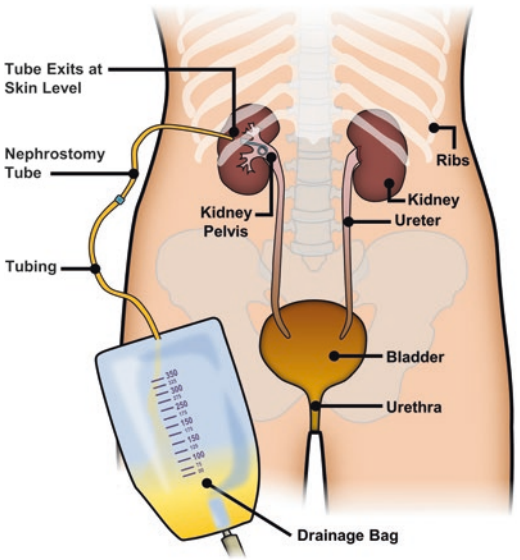
The urinary system has several parts; two kidneys, two ureters, one bladder, and one urethra. The kidneys sit at the back of the body, one on each side, just underneath the ribcage. They filter waste products from the blood into urine. Urine produced in the kidneys flows down a small tube called the ureter and into the bladder. When a person passes urine, it leaves the bladder through a tube called the urethra. Sometimes, a kidney or bladder stone, infection, injury, or tumor can block this flow of urine. To restore the flow, a small catheter (called a nephrostomy tube) is put through your skin in your lower back and into the kidney. Nephrostomy tubes are mostly temporary but can be permanent.

What Is a Nephrostomy Tube?

A nephrostomy tube is a thin plastic tube (catheter) that is inserted through the skin on your lower back and into the pelvis of the kidney. As seen in the picture, the tube redirects urine from the kidney into a drainage bag outside the body. The tube helps drain the build-up of urine in the kidney. The tube will also prevent kidney damage due to urine backing up from the bladder into the kidney. An ultrasound finds the kidney and an X-ray helps guide the doctor to the place to insert the nephrostomy tube into the kidney. A small stitch (suture) will hold the catheter in place on the surface of the skin. The bag has a tap or port for emptying the urine.

The end of the nephrostomy tube can be either:

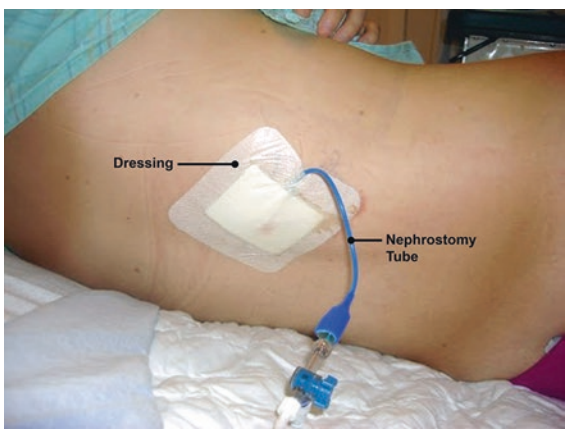
1. Capped, which means there is a plug in the end of the tube which prevents urine from draining. You will pass urine in the normal way.
2. Connected to a bag called a nephrostomy bag that will collect the urine draining from your kidney through the nephrostomy tube. You will need to empty the bag frequently so it does not become heavy, or cause the nephrostomy tube to fall out.



How to Care for a Nephrostomy Tube?

Since a nephrostomy tube goes directly through the skin into the part of the kidney that collects urine, it needs special care and protection, to prevent problems. A family member or a friend should learn how to change the dressing.

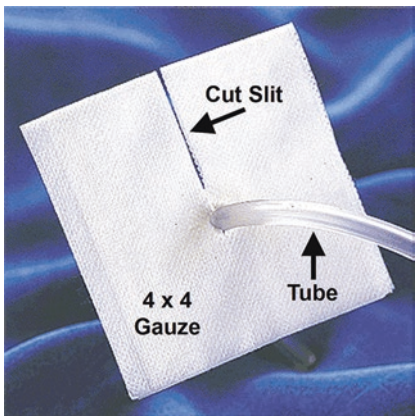
- Keep the dressing around the place where the tube leaves your body dry and secure. This will help prevent infection. If it is loose, put more medical tape over the edges. If it is wet or soiled, it needs to be changed. Change the dressing every 3–5 days.
- If your nephrostomy tube has a cap on the end, tape the tube to your side inside the dressing.
- If your nephrostomy tube is draining urine, the end of the tube will be connected to a leg drainage bag during the day and to a larger bag at night. You can keep the drainage bag under your clothing strapped to your thigh or attached to clothing with a safety pin. Do not leave the bag hanging, because the weight of the urine and any tugging on the bag can cause your nephrostomy tube to fall out.
- If the cap or the leg bag/drainage bag becomes disconnected from the nephrostomy tube, clean the connection site with alcohol, let it dry, and reconnect it.



- You can shower and bathe, 48 hours (h) after tube insertion, but try to keep the tube dry. Protect the area including the dressing with plaster wrap. After a shower, put on a new dressing over the tube. After 14 days, you can shower without protecting the tube.
- Do not worry if the suture keeping the tube in pulls out or breaks. If the suture does pull out, put on a new dressing, tape it, and use tape to keep the tubing in place.
- Empty the drainage bag when it gets more than half-full.
- Do not swim as long as the tube is in place.

How to Change a Nephrostomy Tube Dressing

1. Wash your hands before changing the dressing or emptying the drainage bag.
2. Empty the drainage bag.
3. If someone is helping with changing the dressing, lie on your side with the nephrostomy tube facing upwards. If alone, stand or sit in front of the mirror and turn your body so you can see the nephrostomy tube in the mirror.
4. Carefully remove the old dressing. Gently pull the tape down towards the feet. Be very careful not to pull on the tube itself. Throw the old dressing away.
5. Check the skin around the tube. Does it look red or swollen? Is it painful to touch? If so, contact the doctor or nurse as this could mean you have an infection.
6. WASH YOUR HANDS AGAIN!
7. Set out all the items needed to put on a new dressing:
   - 4 × 4 gauze pads. The number of gauze pads you will need depends on how much oozing is around the tube. Open packages without touching the sponges.
   - Clean scissors (if necessary, wash with soap and hot water before use)
   - 2″ silk medical tape
   - One clean washcloth
   - Antiseptic soap (e.g., Dial)
   - One or two ABD (Surgipads) may be needed if the dressing becomes frequently wet.
8. Pour some antiseptic soap onto a clean washcloth and wet with warm water.
9. Clean the skin around the nephrostomy tube gently. Peel away any existing adhesive. Rinse the washcloth with warm water and wipe the soap off the skin. Allow the skin to dry.
10. Take the scissors and cut the 4 × 4 gauze as shown in the picture to the right.
11. Place the 4 × 4 gauze so that it surrounds the nephrostomy tube.
12. If the dressing is becoming wet often, place 1 or 2 ABD pads (Surgipads) on top of the 4 × 4 gauzes.
13. Tape the dressing in place with 2″ silk medical tape. All edges of the dressing should be taped on the skin.
14. When using a leg drainage bag or large bag, make sure the drainage tubing is taped to the hip so there is no weight on the tube.



When to Follow-Up?

An X-ray study called a nephrostogram may be done in 5–7 days and/or when you are scheduled to return to the office for tube change.

Helpful Tips

- Drink between *six* and *eight*—8-oz drinks or a total of 48–64 oz of liquids each day.
- If you feel that you have a fever, take your temperature. If your temperature is higher than 100.5°F, call your doctor or nurse.
- If the skin around the tube is sore or red, a skin protective wipe (e.g., Cavilon) should be used for further skin protection and to allow healing.
- If the tube is not draining, check to see if the tube is kinked, bent, blocked, or has become dislodged.

When to Call the Doctor?

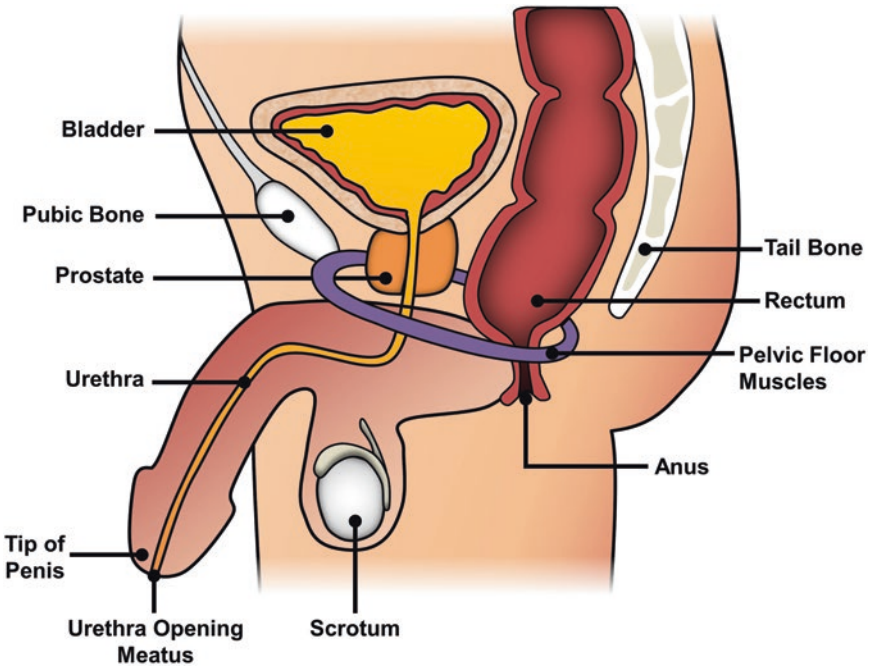
- If you have severe pain in or around the kidney, this may mean you have an infection or the tube is blocked.
- If the tube falls out.
- If there is a sudden increase in drainage of urine on the dressing. This may mean that the tube is blocked and urine is leaking around the tube rather than through it.
- If the nephrostomy tube does not drain. This could mean that the tube is either blocked or dislodged.
- If redness, swelling or pus-like drainage is coming out of the insertion site. This may indicate an infection.

Adapted from: Bailey L & Jaffe WI. Obstructive uropathy. In DK Newman, JF Wyman, VW Welch (Eds). Core Curriculum for Urologic Nursing (1st ed., pp 412, 2017), Pitman, NJ: Society of Urologic Nurses and Associates, Inc.

Performing Meatal Dilation Patient Education Tool

What Is a Meatal Stenosis?

Your urethra is a tube that starts at the base of your bladder and ends with an opening, called the meatus. This opening is where the urine comes out. The meatus and any place along the urethra can narrow and close. If the narrowing is in the urethra it is called a "stricture." If the narrowing is near the meatus, it is called a "metal stenosis." Sometimes stenosis can be so severe that the meatus opening becomes very small, like a pinhole, and you will have a difficult time passing urine.



What Causes This?

A stenosis can be caused by trauma to your urethra, the swelling of the tip of your penis or an infection.

How Do I Know If I Have This Problem?

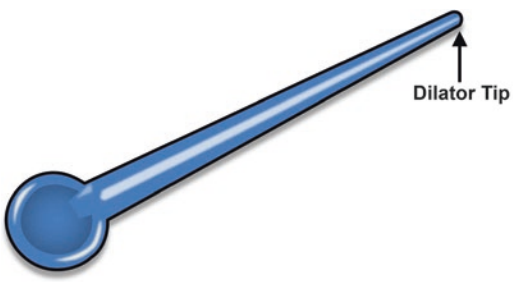
When you are urinating, you may start noticing that the stream of urine is slow or sprays. You may notice that once you are done urinating, urine sort of "dribbles" out, or it may take a long time for you to urinate. Do not strain or bear down when urinating. In severe cases, your flow of urine may just stop or not even start.

What Is the Treatment?

You will need to dilate or widen the end of your urethra. This when you pass a small dilator into the opening of your urethra and pass it beyond the part that is closing.

What Equipment Do I Need?

- Meatal-urethral dilator (usually blue)
- Soap and water
- Water soluble lubricant such as Surgilube or K-Y Jelly
- Clean paper towel



How Do I Dilate?

1. Wash your hands for 30 seconds (s).
2. Gather the equipment and place it on a clean paper towel (or another clean surface).
3. Wash your penis with soap and water.
4. Lubricate the dilator from the tip down the length of it.

5. Carefully insert the tip of the blue dilator into the opening at the tip of your penis and continue to push it in slowly. Push it in about 1 inches, then slowly remove it.
6. After using, clean the dilator with soap and water. Dry it completely and store it in a clean plastic bag.

When Do I Call the Doctor?

- *Bleeding*: When you insert the dilator, you may see a small amount of blood. Do not be alarmed, it will stop. But if it does not stop, call your doctor or nurse.
- *Infection:* You should not get an infection as long as you wash your hands before inserting the dilator. If your temperature is greater than 100.5°F; or you have chills, call your doctor or nurse.
- If you are unable to insert the dilator or have severe pain in your penis, call your doctor or nurse.

Remember

- Dilate your urethra once a day, or as often as directed by your doctor or nurse.
- Be sure to keep your follow-up appointment with your doctor or nurse.

Adapted from: Bailey L & Jaffe WI. Obstructive uropathy. In DK Newman, JF Wyman, VW Welch (Eds). Core Curriculum for Urologic Nursing (1st ed., pp 421, 2017), Pitman, NJ: Society of Urologic Nurses and Associates, Inc.

Urinary Drainage Bags

5

Steven J. Weissbart, Carolyn B. Kaschak, and Diane K. Newman

Overview

Men and women who require catheters, stents, and tubes for urinary tract management rely on drainage bags to adequately store or collect urine. Numerous types and styles of urinary drainage bags are available. Drainage bags possess different features that aid in usability and may help prevent bacterial colonization and infection of the urinary system. Appropriately selecting urinary drainage bags for patients can positively impact quality of life, and thus, healthcare providers should be knowledgeable about the different types available. This chapter reviews the main types of urinary drainage bags: nighttime/bedside bags, leg bags, and nephrostomy bags. Urinary drainage bag complications, research and education are highlighted.

Definition

Urinary drainage bags (UDBs) are containers that attach to urinary catheters (e.g., indwelling urethral or suprapubic catheters, external male catheters or pouches) to collect and store urine. A UDB can be disposable, (the most popular) or reusable. Most disposable UDBs are labeled by manufacturers for "single-use." However, patients with long-term indwelling urinary or external catheters often wash and reuse their UDBs, despite the manufacturers recommendations.

Indications

In order to eliminate toxins and maintain homeostasis, humans rely on a sophisticated excretory system to safely store urine until deemed socially acceptable to void. Worldwide, tens of thousands of men and women cannot satisfactorily store and/or eliminate urine in a physiologic manner and instead use artificial excretion methods, such as synthetic urinary catheters [1–4]. Urinary catheters come in a variety of shapes, sizes, and packaging, and were reviewed in detail in Chaps. 1, 2, 3, and 4. Although urinary catheters serve as adequate conduits for urine to leave the body, the vast majority require the use of a UDB for urine storage and collection. Without a functioning reservoir for urine storage, men and women who use urinary catheters may experience considerable morbidity from skin breakdown resulting from skin contact with urine. Thus, essentially all men and women using chronic indwelling urinary catheters require the use of a UDB, except for those who plug and intermittently unplug their catheter.

Types

As patients have different urinary tract pathologies, medical comorbidities, and lifestyles, there is no single UDBs that can be universally utilized by patients using urinary catheters. Instead, UDBs should be selected for patients based upon a host of factors including the type of urinary catheter needed (e.g., to monitor urine output), patient habits, functional ability, cognitive ability, attitudes and costs. Unfortunately, urinary tract infections (UTIs) are a considerable risk of urinary catheter use; however UDBs characteristics and particular cleaning methods may mitigate UTI risk for some patients. Therefore, healthcare providers should be knowledgeable

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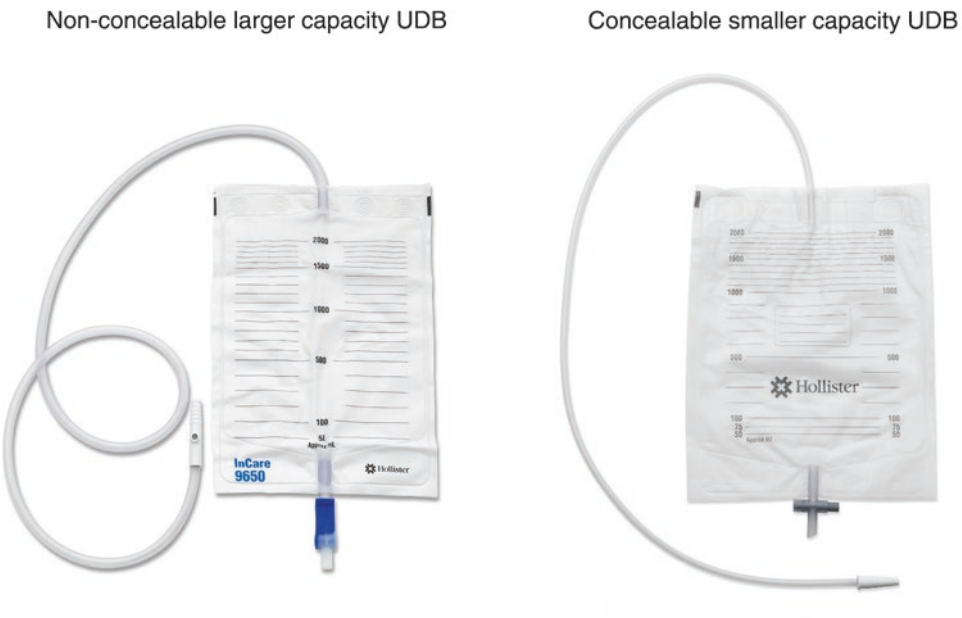

Fig. 5.1 Types of UDBs, non-concealable, concealable—Courtesy of Hollister Inc.

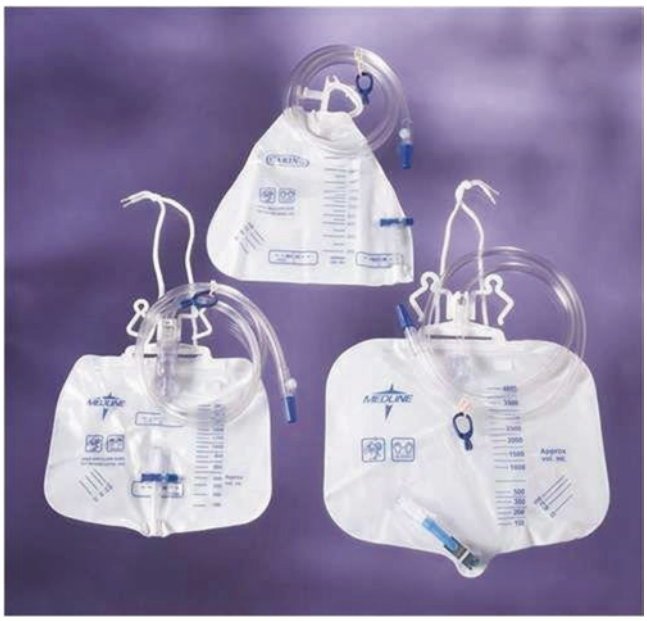

Fig. 5.2 Disposable overnight or large capacity UDBs—Courtesy of Medline

about the different types of UDBs, including their advantages, disadvantages and cleaning methods.

The volume of urine a drainage bag can hold is related to a UDB's size. Additionally, a UDB size may either forbid or facilitate bag concealment and freedom of movement. Therefore, bag size is extremely important to consider when selecting a UDB for a patient. Although UDBs sizes vary, they generally can be categorized into two types (see Fig. 5.1): bags that cannot be worn and concealed, and bags that can be worn and concealed.

Drainage bags that cannot be worn and concealed are commonly referred to as "nighttime or overnight bags," "large capacity bags," or "bedside bags" (see Fig. 5.2) (although these designations may be misnomers as these bags may also be used during daytime hours and/or away from beds). Drainage bags that can be worn and concealed are commonly referred to as "leg bags" (although this designation may also be a misnomer in some cases as not all concealable bags attach to legs) (see Fig. 5.3) or abdominal bags, also known as "belly bags." (see Fig. 5.4)

The most commonly used UDBs are disposable products, but there are reusable UDBs that can be washed and reused for a longer period of time (see Fig. 5.5). They are mainly latex, though some are silicone. It is recommended that reusable UDBs be replaced every 30 days. These bags are commonly used with external male catheters (see Chap. 3) and tend to be smaller capacity bags (e.g. <500 milliliter (ml)) (see Fig. 5.6).

There are two main factors when deciding to use any type of UDB: manual dexterity and lifestyle. Patients may also alternate between the use of a leg bag, a nighttime bag, and a belly bag. Manual dexterity should be evaluated and considered in all patients. Men and women with impaired hand movement may be challenged by emptying their drainage bags and may need to rely on caregivers to empty their bags. As leg bags are smaller and require more frequent emptying, a nighttime or belly bag may be more appropriate for these men and women. The cognition of the person emptying and cleaning a UDB is an additional factor to consider, and patient lifestyle is a highly important factor to consider when choosing a drainage bag. Men and women with active lifestyles may prefer an abdominal bag or leg bag to improve their freedom of movement and to keep their urinary catheters and drainage bags hidden.

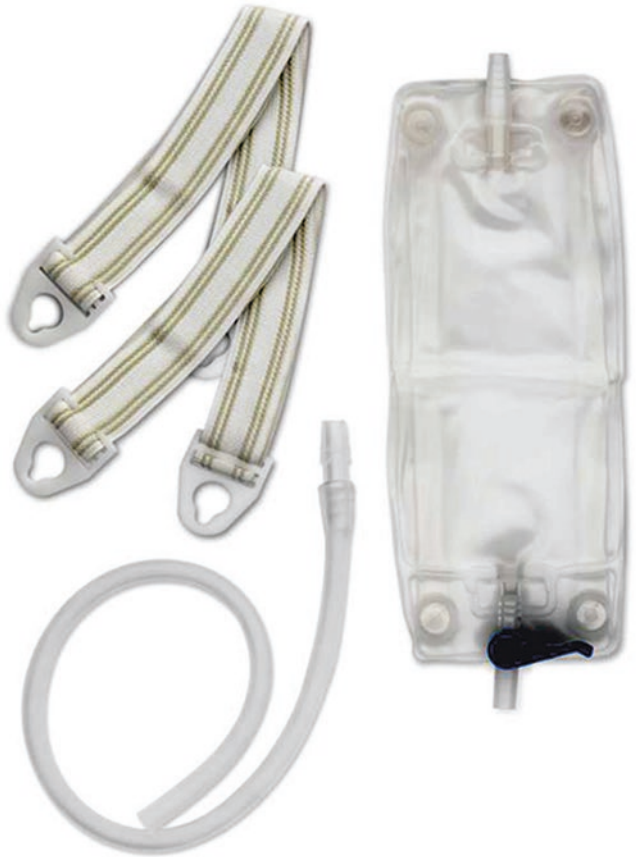

Fig. 5.3 Leg bag with straps and extension tubing—Courtesy of Hollister Inc.

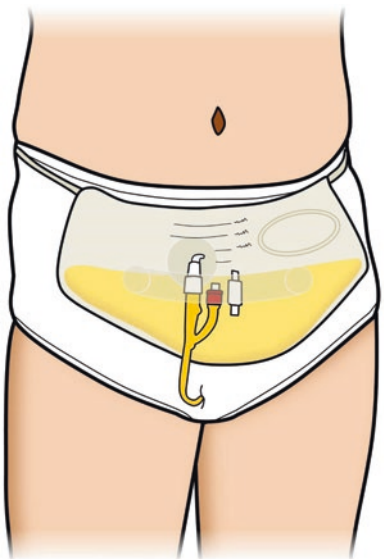

Fig. 5.4 Abdominal bag (belly bag)—Courtesy Diane K Newman, DNP Corp.

However, as nighttime urine production is approximately 50–60 ml/hour, individuals using leg bags during the day may elect to switch to a nighttime bag or belly bag to prevent sleep interruption.

Fig. 5.5 Reusable Latex bag with tubing—Courtesy of Coloplast Corp.

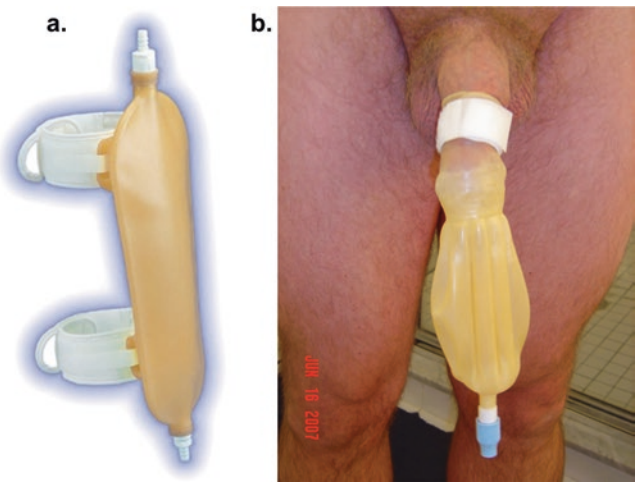

Fig. 5.6 (**a**) Reusable small capacity UDBs—Courtesy of Urotex, (**b**) External male catheter with small capacity drainage bag, AlphaDry—Courtesy of UroDry LLC

Patients with nephrostomy tubes commonly use a specific drainage bag called a nephrostomy bag (see Fig. 5.7). These bags are relatively similar to leg bags, with the exception of tubing specifications, that will be discussed in the *designs* section of this chapter. Depending upon the type of nephrostomy tube being utilized, nighttime bags and/or leg bags may also be connected to nephrostomy tubes and serve as "nephrostomy bags."

Materials

For all types of UDBs, healthcare providers should be reminded to ask about an allergy to latex. Although most disposable UDBs are latex free and made of polyvinyl chloride, some latex UDBs are still available for order. Latex is commonly used for reusable bags (see Figs. 5.5 and 5.6). Leg bag straps may also be made of latex.

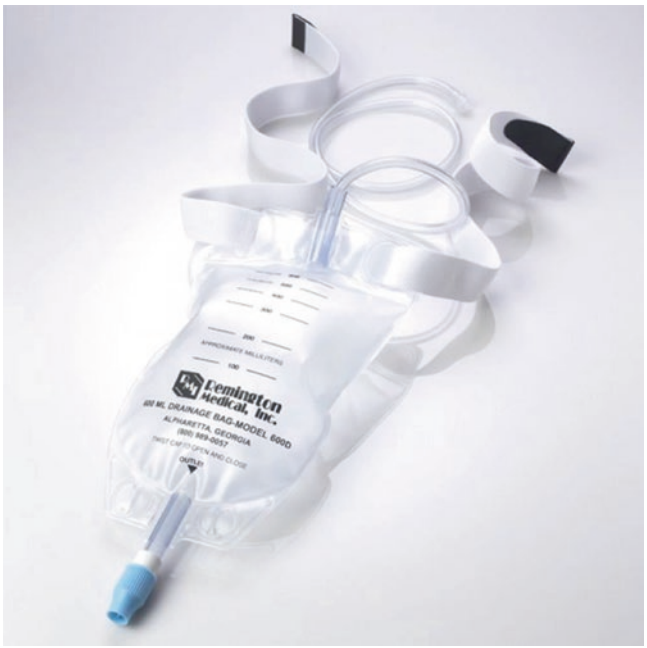

Fig. 5.7 Remington nephrostomy bag with straps—Courtesy of Urotex

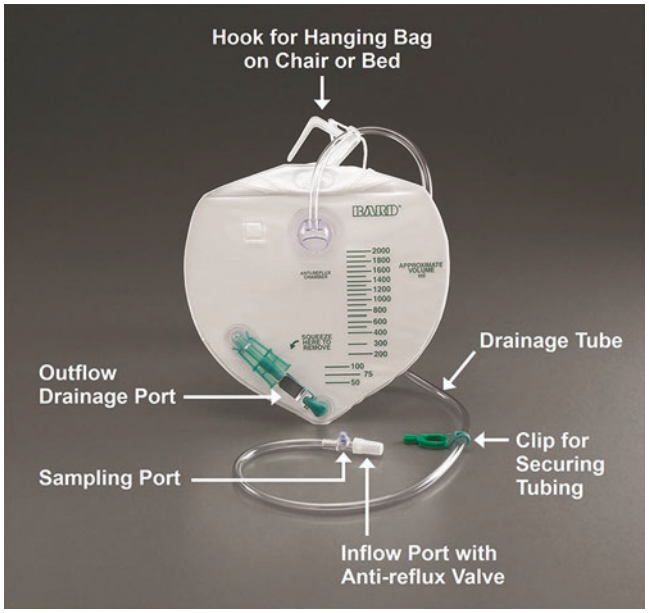

Fig. 5.9 Overnight drainage bag with identified components—Courtesy of C.R. Bard, Inc.

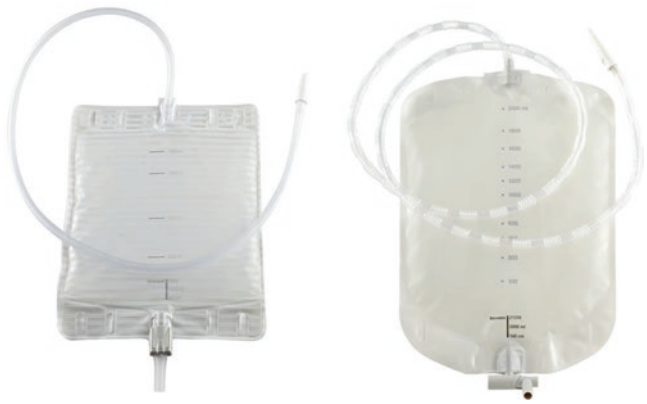

Fig. 5.8 Bedside overnight UBD with short (*left*) and long (*right*) tubing—Courtesy of Coloplast Corp.

Designs

Nighttime bags/bedside bags generally come in a standard design (Fig. 5.8). They are usually cylindrical bags that hold approximately 2000 ml of urine and contain separate inflow and outflow ports (see Fig. 5.9). The inflow port receives urine from clear tubing, which attaches to the catheter. The inflow port also typically contains an anti-reflux device that prevents urine in the drainage bag from reentering the drainage tubing and catheter. Many UDBs have a breather patch and are vented to prevent excessive negative intravesical pressure, which can occur as a result of gravity pulling urine from the bladder. Nighttime bag/bedside bag tubing is typically a few feet long, and the proximal end of the drainage bag tubing has a graduated nozzle that allows for easy connection to the urinary catheter. Often a clip is attached to the tubing, which can be used to secure the tubing to a bed sheet. Additionally, most bags have straps that can be used to suspend bags from beds or chairs. Many bags have a urine sampling port that is incorporated into the tubing. These sampling ports allow clinician to obtain a urine sample without disconnecting the tubing and opening the system which increases infection risk. The acute care setting uses indwelling catheter systems that have the bag preconnected to the catheter (see Chap. 1) and contain a separate collection meter, which allows for accurate measurement of urine output (see Fig. 5.10).

Other nighttime bags/bedside bags do not have a distinct collection meter but have marks on the bag itself to allow for urine output measurement. Accurately measuring urine output is important for inpatient care. Several outflow port devices are available for UDBs, including the lever-type valve, T-bar valve, slide valve, push–pull valve, twist valve, and clamp valve (see Fig. 5.11a–d). Patients with limited manual dexterity may find the lever-type valve to be the easiest to use. For patients concerned about self-image, urinary drainage bag covers are available.

Leg bags come in a variety of sizes, shapes, and materials (see Fig. 5.3). Compared to nighttime bags/bedside bags, they hold smaller volumes of urine (approximately 500 ml). They may be horizontal or vertical and are secured to the leg (calf or thigh) with elastic, mesh, or Velcro™ straps. A knitted bag or a cloth undergarment specifically designed to secure the

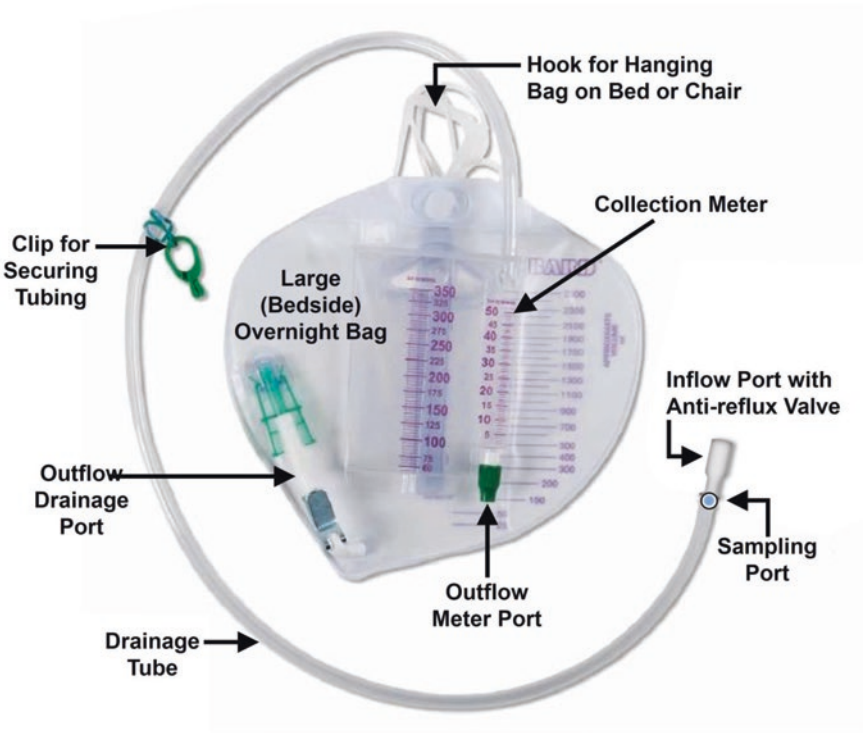

Fig. 5.10 Bedside drainage bag with urine meter—Courtesy of C.R. Bard, Inc.

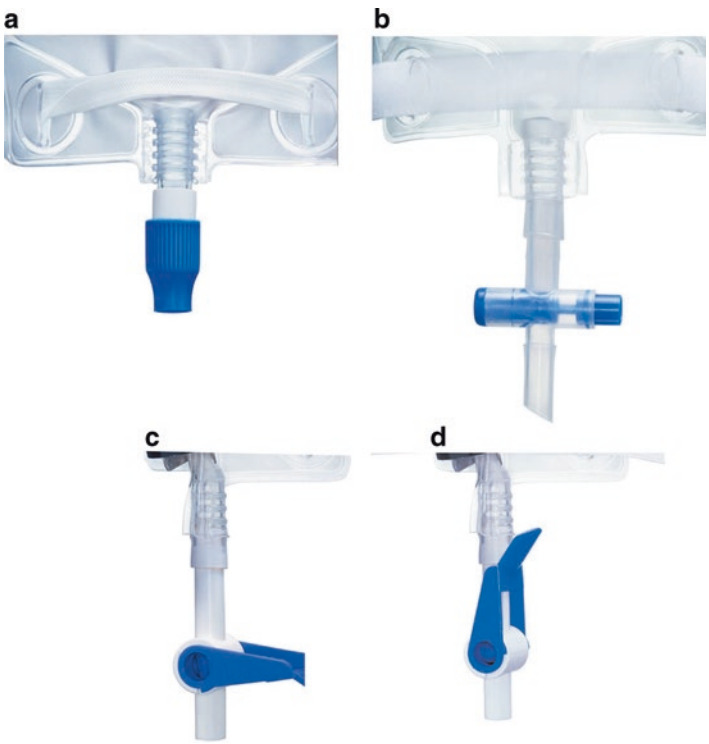

Fig. 5.11 (**a**) TwistPort: twisted to open and close, catheter valves (**b**) T-Bar Closed-Port: pushed in one direction to open and the other direction to close, (**c**) Lever Port: pulled down to empty, (**d**) Lever Port: pulled up to close

bag can be used (see Figs. 5.12 and 5.13), or the bag can be enclosed in a stockinet holder (see Fig. 5.14). Some bags are made of a non-woven material (see Fig. 5.15). Men with an indwelling urinary catheter post-prostatectomy preferred non-latex cloth-backed leg bags with elastic/cloth straps over latex leg bags [5]. Rubber straps are still available but these can be constrictive around the thigh or lower extremity.

These bags may be secured to essentially any part of the leg. (For the remainder of this section, leg bags will refer only to those bags that are secured to patients' legs.)

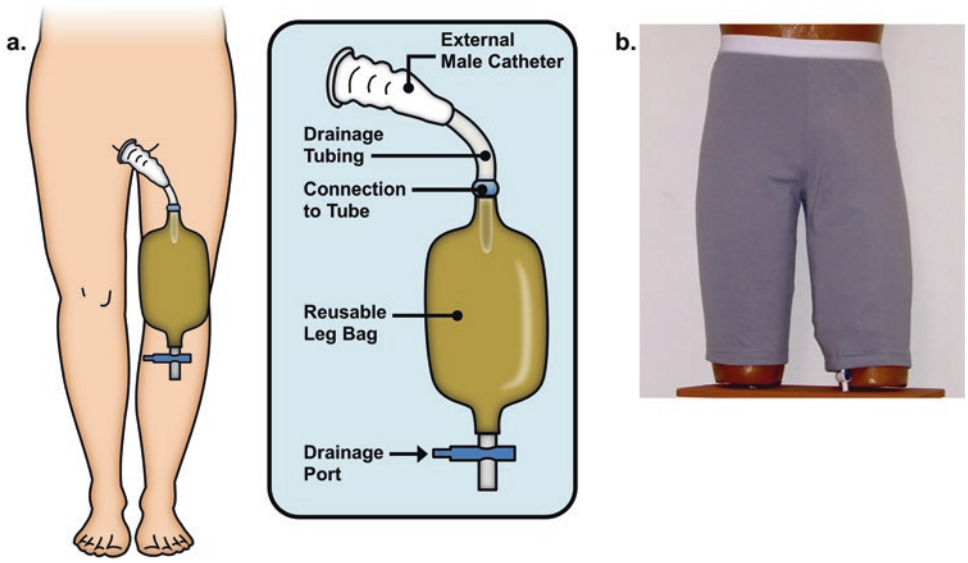

Fig. 5.12 UroBag™ System: Self-adhesive MEC, reusable Latex 700 ml Leg Bag with Leg bag holder cloth undergarment—Courtesy of Uro Concepts, Inc.

Fig. 5.13 Overnight reusable drainage-bag with undergarment bag holder—Courtesy of Arcus Medical

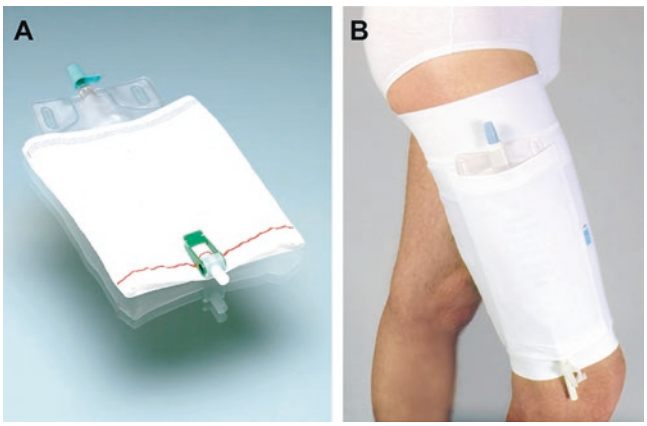

Fig. 5.14 (**a**) Cloth bag sleeve (**b**) Thigh cloth bag holder

Fig. 5.15 Non-woven 250 ml cloth leg bag designed to wear horizontally on the upper thigh—Courtesy of Coloplast Corp.

Although it is often easiest to secure a leg bag to the calf, women who wear skirts may prefer to secure a leg bag to the thigh. Similar to nighttime bags/bedside bags, leg bags typically have separate inflow chambers which can reduce the sloshing effect in the bag (Fig. 5.16). Some bags are intended to conform to the thigh, calf, abdomen, or knee. The inflow port is attached to tubing, which attaches to the urinary

catheter. This tubing comes in various lengths (4–45 centimeter (cm)), as patients wearing leg bags on their calves require longer tubing. Most tubing is 8 millimeter (mm) in diameter and some have an anti-kink feature. Some leg bag tubing also contains urine sampling ports. Leg bags also come with various outflow port designs, similar to overnight bags. But using the term "leg bag" to describe all types of UDBs that can be worn and concealed is somewhat of a misnomer.

Abdomen bags are UDBs that are secured to the lower abdomen, thus the term "belly bag." They can also be worn and concealed (see Fig. 5.17). Abdomen bags have two main advantages over traditional leg bags (that strap to patients' legs): size and comfort. Abdomen bags, such as the "Belly Bag®," may have larger capacities than traditional leg bags. These bags have a one-way inlet valve that prevents urine reflux. Abdominal bags are secured to the abdomen with a soft expandable belt which eliminates problems associated with traditional leg bags, such as inadvertent catheter extraction and leg bruising from securement straps. They also typically have soft, non-woven backings to prevent perspiration, which can lead to skin irritation and bag slippage. On the other hand, some patients may find abdominal bags to be uncomfortable and may prefer traditional leg bags. As there is no UDB that is universally best for all patients, the optimal drainage bag for an individual patient is often found by trial and error.

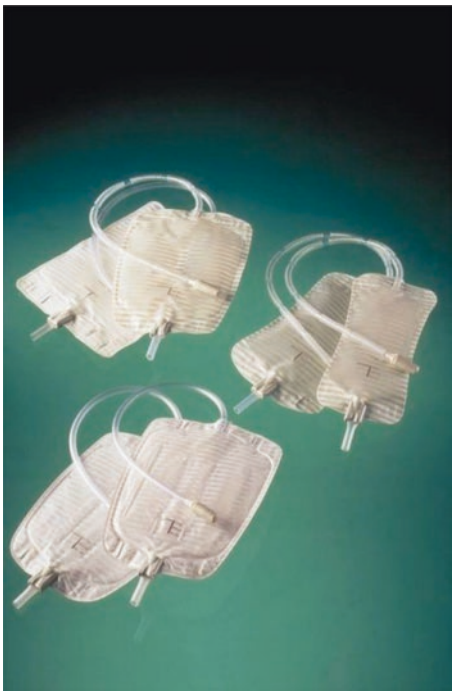

Fig. 5.16 Bags with contoured separate chambers—Courtesy of Coloplast Corp.

Nephrostomy bags are relatively similar in design to leg bags (see Fig. 5.18). These bags typically also hold approximately 500 ml of urine and can be attached to the leg or the abdomen via straps, belts, or garments. They may also possess an anti-reflux mechanism. The most significant design difference between nephrostomy bags and legs bags is the bag tubing. Typically, nephrostomy bag tubing has a smaller diameter. In addition, while a leg bag usually attaches to the urinary catheter via a graduated nozzle, nephrostomy bags are usually attached to nephrostomy tubes via a male Luer Lock connector. At times (e.g., after renal stone surgery), patients may have an indwelling urinary catheter or Council catheter as a nephrostomy tube. In these instances, a nighttime bag or leg bag can be connected to the patient's "nephrostomy" and serve as a "nephrostomy bag."

Techniques/Procedure for Use

Patients and healthcare providers should wash their hands with antibacterial soap prior to connecting a UDBs to a catheter or emptying a UDB. Additionally, healthcare providers

Fig. 5.17 Belly Bag® 1000 ml capacity—Courtesy of Teleflex

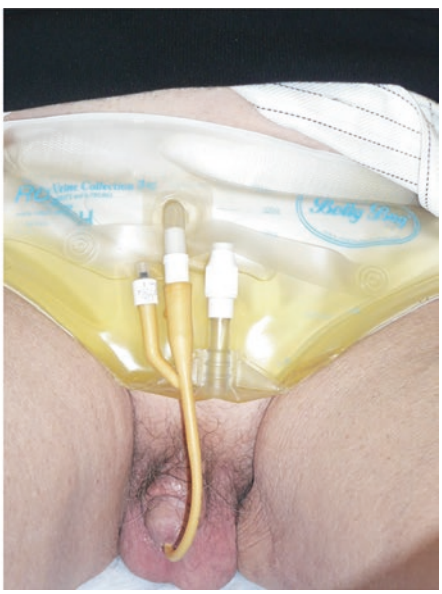

Fig. 5.18 Nephrostomy bag

Fig. 5.19 Purple Bag—Courtesy of Eric Rovner

should wear gloves. Disposable absorbent pads (i.e., blue chucks) should be placed in the surrounding area in case of urine leakage. To connect a UDB to a catheter, insert the graduated nozzle on the proximal end of the UDB tubing into the distal end of the catheter. Then properly secure the catheter, tubing, and bag to the patient's leg and/or bed or chair. Then open the drainage port and direct the urine into the toilet or container. Once the bag is empty, an alcohol pad can be used to wipe the outflow port. Then close the outflow port and measure and empty the container of urine. After emptying drainage bags, one should ensure that there are no kinks in the tubing and that the UDB and tubing are not on the floor.

Problems

Complications

Urethral trauma can be a complication of UDBs. When filled, a UDB is heavy and can put traction on the urethra if not properly secured. Other UDB complications include skin changes (on legs) and bruising, which can occur from leg bag straps that are too tight and restrict circulation. Additionally, nephrostomy tubes may become dislodged if the UDB is not properly secured.

Adverse Events

Urinary drainage bags are associated with several adverse events. Catheter-associated urinary tract infections (CAUTI) are a significant problem in many healthcare systems and have been associated with considerable adverse outcomes, ranging from increased length of hospital stay to mortality [6]. Presence of bacteria within and on the UDB is thought to play a considerable role in CAUTI development. Obstruction, leakage, and poor UDB concealment comprise other adverse events. Leg bags can be hard to conceal, can bulge beneath clothing as they fill with urine, and can be associated with audible sloshing of urine [5, 7, 8]. Kinks in the drainage tubing and overly filled bags are two common causes of obstruction and leakage. Avoiding urine-filled dependent loops in the drainage tube can potentially decrease the likelihood of a CAUTI, especially in indwelling urinary catheters [9, 10].

Purple urine bag syndrome (PUBS) occurs when a urinary drainage bag turns a purple discoloration upon use (see Fig. 5.19). The discoloration is most commonly seen in the tubing and drainage bags; however, the urine may have a purple discoloration as well. It is an uncommon condition occurring mainly in chronically catheterized patients and is sometimes associated with a UTI. Globally, the prevalence of PUBS reported varies (8.3–9.8%) among hospitalized patients. In patients with prolonged catheter use for months, such as those in nursing homes, the prevalence is higher, ranging from 16.7–42.1%.

Although this syndrome is considered benign, it may be alarming to patients and caregivers, and it may also be indicative of urinary tract colonization or infection. The pathogenesis of purple bag urine syndrome is related to tryptophan metabolism. Dietary tryptophan is converted to indole via bowel metabolism. Indole is then conjugated to indoxyl sulfate (indican) by the liver. Indican is excreted into the urine and metabolized by bacterial enzymes (sulfatise and phosphatase) into indigo (blue) and indirubin (red) [11, 12].

Thus, the occurrence of purple urine bag syndrome indicates bacterial presence in a urinary drainage bag. However, deciphering between urinary tract colonization and infection often proves to be a dilemma. Medications can also cause urine discoloration (e.g., rifampin, ibuprofen, phenytoin, phenazopyridine, propofol, and L-dopa).

PUBS is an uncommon manifestation of a UTI but the prevalence is increasing [13]. It is associated with the female gender, alkaline urine, UTI, chronic kidney disease, dementia and use of polyvinyl chloride urinary catheters and bags [14]. Chronic constipation could be a contributing factor if it results in prolonged exposure of tryptophan in bowel residue due to bacterial action.

Prevention

Urethral trauma and nephrostomy tube dislodgement can be prevented by properly securing UDBs and catheters. Several straps, hangers, and holders are available for use. Restriction to leg circulation and resulting skin changes can be prevented by gently fastening leg bag straps. Support garments and sleeves can also be used instead of straps.

Considerable efforts have been devoted to preventing CAUTI occurrence. As pertains to UDBs, anti-reflux bags, single use bags, closed urinary drainage systems, and UDBs with urine sampling ports have all been employed in an attempt to reduce CAUTI rates. Additionally, proper UDB cleaning may decrease the chance of developing a CAUTI.

As bacterial colonization occurs in essentially all men and women using catheters in the long term, anti-reflux UDBs attempt to reduce CAUTI rates by preventing backflow of colonized urine from the drainage bag into the bladder. Employing single use UDBs may prevent drainage bag bacterial colonization and CAUTI, although insurance companies may not reimburse for these types of bags. Closed indwelling urinary drainage systems, which are almost universally used in current times, minimize the risk of a CAUTI by having the urinary catheter connected to a drainage bag, forming a closed single system; previously, catheters would drain into an open container (i.e., open system), which predisposed individuals to infection. A leg bag cannot be characterized as closed because of the need to regularly open the leg bag for drainage and in most cases, to switch to an overnight drainage bag. To minimize opening a catheter system, a leg bag can be attached to a larger bag for overnight drainage (see Fig. 5.20). The addition of a urine sampling port in the UDB tubing allows healthcare providers to obtain a urine sample without disconnecting the system, which can predispose patients to infection. Additionally, for patients who switch from a daytime leg bag to a nighttime bag, a silicone connecting tube can be used to connect the leg bag outflow port to the nighttime bag and eliminate the need to disconnect the system. Other methods to prevent CAUTIs include emptying the UDB before it is full and ensuring that bags are positioned below the level of the bladder at all times.

Proper UDBs cleaning is also important (see Urinary Drainage Bag Care Patient Education Tool). Two commonly used solutions for urinary bag cleaning include a bleach based solution and a vinegar based solution. These solutions

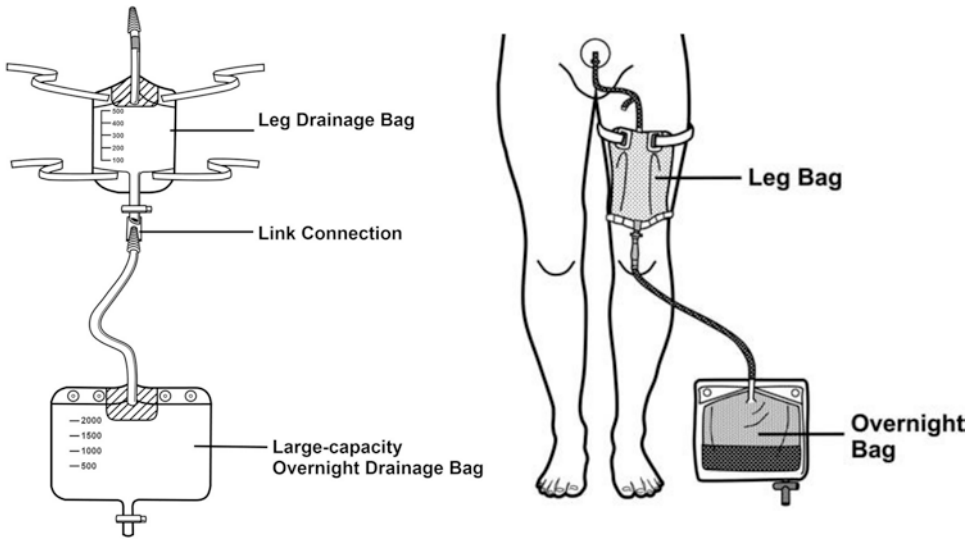

Fig. 5.20 Closed urine-drainage system is achieved by connecting catheter to a valve (Fig. 5.21) or a sterile drainage bag only broken when the leg bag is changed. In this figure, the leg bag port is open and the overnight bag is attached to the outflow port of the leg bag—Courtesy of Robin Noel

are simply made by mixing tap water with household bleach or vinegar. Regardless of the solution used, bags are typically cleaned in the following order:

1. Empty and rinse the bag with lukewarm water;
2. Vigorously shake the bag with clean water inside and drain the water (repeat this step twice);
3. Pour a diluted solution of either household liquid bleach or vinegar on the drainage port, sleeve, cap, and connecter;
4. Pour a diluted solution of either household bleach or vinegar into the urinary drainage bag, shake the bag for 30 seconds (s), and empty the solution;
5. Rinse the bag with soap and water, hang the bag and allow to dry.

UDBs should be cleaned every 5–7 days, and patients should use a new bag if their drainage bag becomes discolored, stiff, leaks or falls apart. Typically, patients should replace drainage bags twice a month.

Selecting a UDB for a patient that has an easy to use emptying device may prevent bag leakage. Aside from allowing a patient to easily empty their drainage bag, a patient must feel comfortable with adequately closing their bag's emptying device to prevent the bag from leaking. Of the many devices in use, the easiest for patients may be the lever-type valve. However, patients may find other emptying devices, such as the T-bar valve, push–pull valve, or clamp valve to be more convenient. Urinary drainage bag obstruction, which most commonly occurs secondary to tube kinking, can be prevented by selecting a bag with appropriate tube length and using bags with corrugated tubing. Poor UDB concealment can be handled in a number of ways. Patients using leg bags may elect to use an abdominal bag. Additionally, bags with fabric backings or bags made of polyvinylidene fluoride (as opposed to polyvinyl chloride) may be less noisy. Some bags also possess internal pockets that divide urine into smaller volumes and prevent noise during patient movement. More frequent bag emptying can also help with noise and/or the appearance of a bulge underneath clothing. Patients may also wish to try different leg locations to help with bag concealment.

Catheter valves may be a reasonable alternative to a UDB and may prevent complications associated with UDB use (see Fig. 5.21). Catheter valves are devices that fit into the outflow tract of an indwelling urinary catheter. These devices feature an open and close mechanism, which allows patients to store urine in their bladders instead of in drainage bags. The catheter valve is kept in the closed position during urine storage and is switched into the open position when patients experience bladder fullness. These devices can be used with both urethral and suprapubic catheters and can also be attached to a nighttime bag during sleeping. Potential benefits of using a catheter valve instead of a UDBs may include: (1) "bladder cycling," which allows maintenance of bladder capacity, function, and tone by permitting periods of urine storage and emptying (2) decreased urethral erosion risk, as there is no added drainage bag weight placing traction on the catheter or urethra, and (3) a potentially decreased risk of CAUTIs as there is no bladder exposure to a colonized UDB. All patients using catheter valves should be instructed on how frequently they need to empty their bladders, especially patients with neurogenic bladders as they may require more frequent bladder emptying.

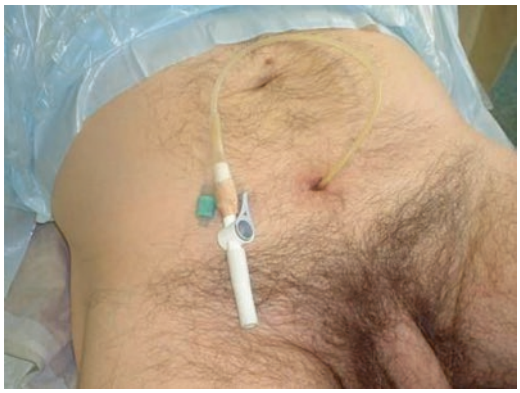

Fig. 5.21 Suprapubic indwelling catheter attached to a catheter valve

Evidence-Base Evidence

Best Practices for Management

There is no best practice statement that comprehensively reviews UDBs management. However, the National Institute for Health and Care Excellence (NICE) guideline on infection prevention and control includes a section on urinary catheters [15]. Pertaining to UDBs, this guideline recommends connecting indwelling catheters to a sterile, closed urinary drainage system or catheter valve to ensure the connection between the catheter and drainage bag remains intact unless another set up is clinically necessary. Positioning the UDB below the bladder keeps the UDB off the floor and emptying the drainage bag frequently allows for flow and prevents reflux. Additional recommendations included not sharing drainage bags among patients, changing the drainage bag when clinically indicated, avoiding contact between the UDB tap and container, and obtaining urine samples via a sampling port.

Aside from the NICE guideline, an article written by Nash suggests the best practice for patient self-cleaning of UDBs [16]. This author largely reviews the work of a prior study conducted by Dille and Kirchhoff (study discussed below) and suggests that common household bleach containing 5.25% sodium hypochlorite is a safe and effective method for bag

cleaning (Dille et al. [17]). Although this solution appears to be efficacious in minimizing bacterial colonization, there is limited high quality data on the ideal care of a UDB, which unfortunately precludes strict evidence-based recommendations on the topic. This gap in knowledge is highlighted by an International Consultation on Incontinence committee report, titled Management Using Continence Products [18].

There is also very little research comparing various leg bag designs. Moody and McCarthy [19] performed semi-structured interviews of 29 leg bag users and 5 caregivers and heath care professionals to identify priorities for product redesign. Users identified some design limitations of currently available leg bags, including (1) reliability of the bag, drainage port, and connecting tubing and connectors to promote urine containment, (2) leg bag securement and (3) discretion to wear under clothing.

Clinical Publications

As previously stated, there is a paucity of high quality (level 1) data regarding UDB management. However, there have been some notable clinical publications that may help guide health care providers in their management of men and women using UDBs. These studies have primarily investigated bacterial colonization and CAUTI rates associated with urinary drainage bag use.

Dille et al. [17] investigated the relationship between UDB wearing time and bacterial colonization. In their study, 54 patients wearing vinyl urinary leg bags and bed bags were randomized to either a weekly bag replacement or a bag replacement at 4 weeks. They found no difference in colonization between the groups, and the authors concluded that it was safe to reuse leg bags for up to 4 weeks. While the study is limited in that both groups of patients had their UDBs decontaminated (with bleach) throughout the study, it would appear that frequent replacement of a UDB is unnecessary. Allepuz-Palau et al. [20] analyzed the Study of Prevalence of Nosocomial Infections in Spain database to assess the relationship between the implementation of closed urinary drainage systems and urinary tract infections. Over a 10-year period, they observed a nearly 20% increase in the use of closed urinary drainage systems, which was associated with a decrease in CAUTIs from 9.2% to 5.6%. Although other factors may have led to a reduction in CAUTIs over the 10-year period, this data supports the use of closed urinary drainage systems. A number of studies have also investigated the ideal UDBs decontamination method. Wilde et al. conducted a systematic review of such studies and interestingly found insufficient evidence in favor of a particular decontamination method [21]. Future research on the topic is clearly needed to help guide health care providers who care for men and women using UDBs.

Research

Some interesting laboratory research pertaining to UDBs, has been conducted that largely focuses on innovations that may reduce UDB bacterial colonization. Wenzler-Röttele et al. [22] studied one such innovation, a UDBs with a double non-return valve. In the laboratory, they compared bacterial colonization rates when using a drainage bag with a double non-return valve to a drainage bag with a single non-return valve and found bladder colonization significantly delayed when using the double non-return valve. Although this data is promising, some believe that anti-reflux valves obstruct urine flow, which may result in patient discomfort and/or CAUTI [23]. Therefore, it may not be advantageous to have a system with two non-return valves. A different group applied an electrical current to UDBs with the hope of eradicating UDB bacteria. They found that applying an electric current to drainage bags was associated with decreased bacterial colonization, especially *P. aeruginosa* [24]. Another innovation to reduce bacterial colonization/CAUTI rates has been the use of a lock-out valve when changing between UDBs (i.e., from leg bag to nighttime bag). Frequently, a patient's closed urinary drainage system is violated when changing between bags; the premise of the lock-out valve is that it maintains a closed system during bag exchange [25]. There is also a leg bag system that monitors the urine bag level (see Fig. 5.22) and sends a signal (flashing amber light, or vibration) to a "controller" when the leg bag is approximately 2/3 full. The bag can be emptied by pushing a button. The leg bag, pump, and discharge tube constitute an integrated, disposable unit. The controller is rechargeable.

Patient Information

Teaching Tools

The majority of companies that manufacture UDBs provide detailed instructions on UDBs care for patients. One such manual, which also includes trouble-shooting tips (e.g., bag leakage and lack of drainage), is referenced here [26]. These manuals can be very helpful in educating patients on proper UDBs use. Additional information on appropriate UDBs care can be found at the end of this chapter.

Education

The Continence Product Advisor website (http://www.continenceproductadvisor.org/), which was made in collaboration with the International Continence Society and other organizations, can be a useful tool for initial education of patients on the different UDB products that are available on the market.

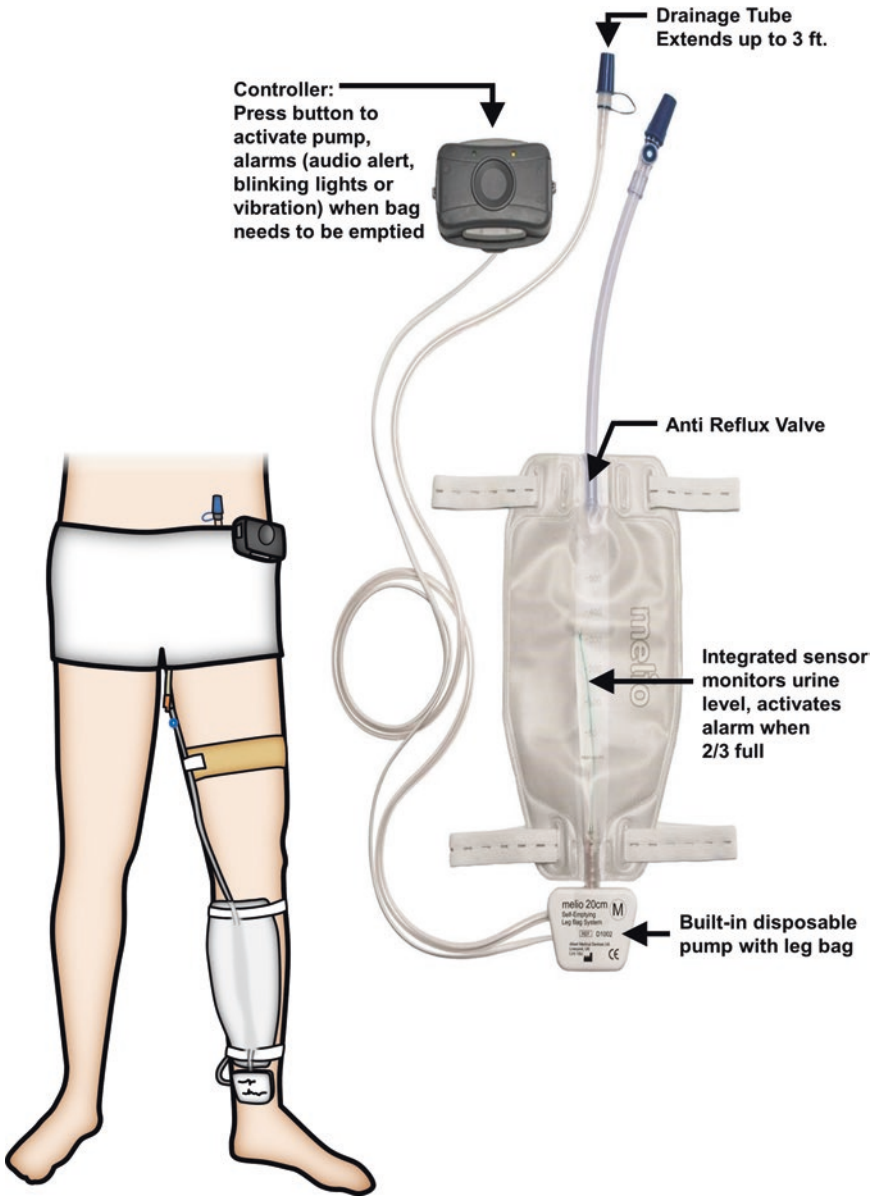

Fig. 5.22 Leg bag system with a built-in sensor that alert when bag needs emptied, Melio™ —Courtesy of Albert Medical Devices

Conclusion

Health care providers should be knowledgeable about the different types of UDBs. A patient's manual dexterity is a key factor in selecting an appropriate UDB for the patient. UDBs possess certain features that may decrease the risk of CAUTI. Proper selection and use of a UDBs can improve the quality of life of men and women who rely on urinary catheters.

Patient Information

Urinary Drainage Bag Care Patient Education Tool.

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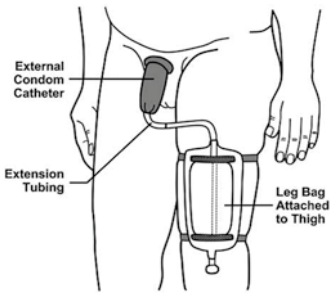
Urinary Drainage Bag Care Patient Education Tool

What Is a Urinary Drainage Bag?

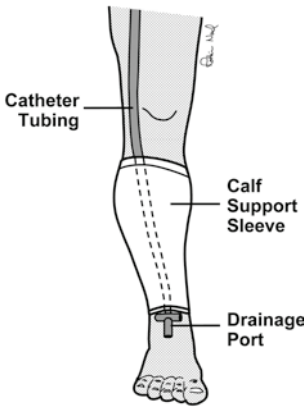
Your catheter will be connected to a drainage bag that will collect the urine that drains from your bladder. There are three types of drainage bags:

- An *overnight drainage bag* is used during the night. It is connected to your catheter by a long tube. This bag holds 1 ½ to 2 quarts of urine. It comes in different sizes (horizontal or vertical) and is made from a variety of materials (silicone vinyl, latex, or rubber). It is bag is usually hung on the side of the bed or a chair or stand. To make sure the urine is draining, always keep the bag below your bladder.

- A *leg drainage bag* is a smaller collection bag for use at home during the day or when you go out of your house. The leg bag has straps which can be wrapped around your leg (at the thigh or calf). The bag is easier to hide under your clothing.



A leg bag is more compact and can be held in place with a net sleeve or stocking as seen in the picture on the right. Do not make the straps too tight because this could slow the blood flow to your leg. Take care of the leg bag in the same way as the overnight drainage bag.



- A *stomach drainage bag*, also called a "Belly Bag," is worn at the waist. The bag has a cloth belt that goes around your stomach and is fastened with a release buckle. A one-way valve keeps the urine from backing up from the bag back into the catheter. The bag is emptied by a drain tube with a twist valve. The bag has a soft backing that is next to your skin.

Emptying Your Drainage Bag

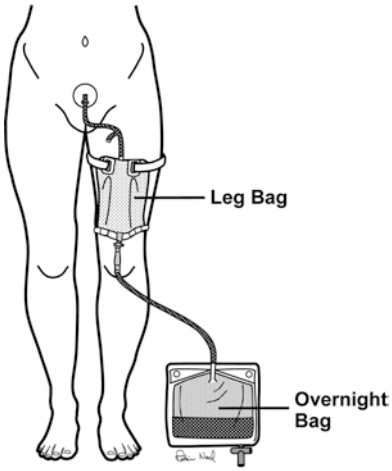
You should empty your drainage bag at least every 4 hours (h) or when it is halfway filled. There are different types of drainage ports or taps that you open to drain the urine. Some twist off, others are a flip-flow or sliding valves. Make sure you can open and close the port easily before going home.

How to Position Your Drainage Bag

If you are using an overnight or leg bag, the position of your drainage bag is important. At night, you can attach the leg bag to a larger-sized overnight bag as shown in the picture to the right.

You must have good drainage to prevent "backflow" of urine. Urine must always drain "downhill," so keep the urine drainage bag below the level of the bladder at all times. This allows the urine to drain by gravity and will prevent it from flowing back into the bladder. As the drainage bag fills with urine, it becomes heavy and can pull on your catheter or drag uncomfortably if not supported. You can support the overnight bag by hooking it on a hanger attached to the bed frame. If you are using a Belly Bag, it should be strapped around your stomach.

Also, make sure the drainage tube does not become bent or kinked, as this will stop the flow of urine.



How to Disconnect or Change Your Drainage Bag

Pinch the catheter tubing between your fingers, above the drainage bag connection, to stop the flow of urine. Using a twisting motion, disconnect the tubing and bag from the catheter. Take an alcohol-soaked pad and clean the end of the new tubing and the connection site of the catheter. Insert the new tubing into the catheter. Using an alcohol-soaked pad, clean the end of the tubing that was removed and replace the protective cap. Save caps to drainage bags to cover ends of tubing when not in use.

How to Clean Your Drainage Bag

Drainage bags can be cleaned and deodorized by filling the bag with a mixture of 1-part vinegar and 3 parts water, then letting it soak for 20 min. After cleaning the bag, wash it with soap and water and dry the bag by hanging it with the emptying spout pointing down. Do not hang the bag over the heat of an oven or radiator. When dry, recap the bag until ready for reuse. If your bag starts to wear out, becomes discolored or stiff, or falls apart, get a new bag. To avoid bladder infections, clean the bag every 5–7 days and use a new bag at least twice a month.

What If I Get an Infection?

If you get repeated bladder infections, spasms, or pain, your nurse or doctor may tell you not to disconnect the catheter from the bag. In such cases, you should use only the overnight drainage bag. Call your doctor or nurse if you have questions or problems.

Absorbent Products for Incontinence

6

Melissa DeMarinis, Tammaris R. Kaschak, and Diane K. Newman

Overview

Absorbent products that collect and contain urine and fecal loss due to bladder and bowel dysfunction are commonly utilized as a first-line defense and daily management option for those individuals experiencing incontinence. Unlike feminine hygiene products that are designed to absorb menstrual blood, these Class 1 medical devices (classified by the United States (US) Federal Drug Administration (FDA)) are specifically designed to absorb and contain urine. Absorbent products are also useful in mitigating the potential clinical complications from incontinence, such as skin irritation and breakdown and the development of tissue injury in the perineal area. High-performing products are also vital in supporting individuals dealing with the stressful psycho-social implications of lower urinary tract symptoms, such as embarrassing visible urine leakage, urinary frequency, unpleasant odors, and social isolation. These products are particularly useful in supporting persons undergoing treatment, who are not candidates for treatments or interventions and, therefore, remain incontinent. To meet the varied needs of individuals and their lifestyles, these products include a variety of designs, absorbency levels and options for use. They are utilized across the continuum of care, from the active and independent consumer at home, to the mostly immobile or bed-bound dependent patient in a clinical care setting.

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There are gender-specific absorbent incontinence products because men and women are likely to prefer different designs. These products can be readily accessed in clinical settings and purchased through retail channels in stores (e.g. grocery stories, pharmacies), or some online. Over the past decade, as acuity levels and comorbidities have increased with the aging population, there is rising demand for even more products, making absorbent products one of the fastest-growing household products [1]. This demand has also led to increased research and continuous innovation by manufacturers to capture more market share, as they invest heavily to out-perform competitors, capture consumer confidence, and increase the conversion rate to their brands.

Absorbent products for incontinence care are designed to absorb or contain urinary leakage, but can also be used for fecal loss in those individuals who are not capable of maintaining continence independently through regular toileting or other measures. Products are constructed of absorbent materials and manufactured to be either disposable or reusable with proper laundering. Disposable absorbent products contain paper-derived fluff and superabsorbent polymers (SAPs) or absorbent gelling material (AGM) to wick urine into the product to contain it, minimizing wetness against the skin and allowing for the absorbance of multiple voids and/or incontinence episodes. Reusable products are composed primarily of absorbent cloth and therefore do not have the technological ability to keep wetness from the skin's surface or absorb multiple voids. Both disposable and reusable products can be readily accessed by clinicians to provide urine and stool containment in all care settings, or purchased by consumers through retail channels in stores or online. There is not a "one product fits all approach" when it comes to absorbent products. Rather they are developed and customized with many features to support the customized care needs of the individual and to maintain the highest levels of comfort and quality of life.

For maximum effectiveness in their ability to absorb, most products are worn close to the body and are known as "bodyworn" garment-like products. There is also a category

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that is not worn against the body, but held in place against the body by resting on a support surface (e.g., underpad or bedpad). Product manufacturers provide indications for use and best practices for the product style and type, to ensure maximum effectiveness. As the prevalence and demand for adult products has grown, the availability of educational resources to support these medical conditions and effective selection and proper use of adult absorbent products for incontinence rose sharply, both in print and online. Today, there are a variety of resources available to support those with urinary incontinence (UI) and fecal incontinence (FI). Accessing information online has never been easier, while protecting the privacy and dignity of potential users. As technology and innovations evolve, manufacturers and brands have invested in connecting with product users. They have sought to remove the stigma associated with absorbent products, by normalizing their use, as well as, the medical condition. While significant progress has been made, the use of absorbent products is still a closely guarded issue that wearers seek to keep private. This need and demand for discretion has driven much of the innovation found in the field.

Indications

Absorbent products for incontinence are indicated for all ages and are designed to support individuals with stress, urgency, and/or mixed UI who have varying severity of urine and/or fecal leakage (see Fig. 6.1). The most common type of absorbent product utilized is an adult brief, a "diaper-like" or "all-in-one" product, similar in design to those used for infants and young children prior to toilet training. This basic concept and technology has been applied to develop products to support all ages and incontinence care needs, taking into account the individual's age, gender, level of mobility, cognition, and care setting. Starting in the 1970s, specific products were developed for adult populations and now feature as much innovation as the baby diaper market. As the US birth rate peaked in 2007, the growth rate for baby products likewise plateaued. Data from *Euromonitor International* indicates that in as little as a decade, sales for adult absorbent products for incontinence could surpass those for babies (see Chart 6.1).

As such, current absorbent products can be utilized by any individual as a main form of management for their

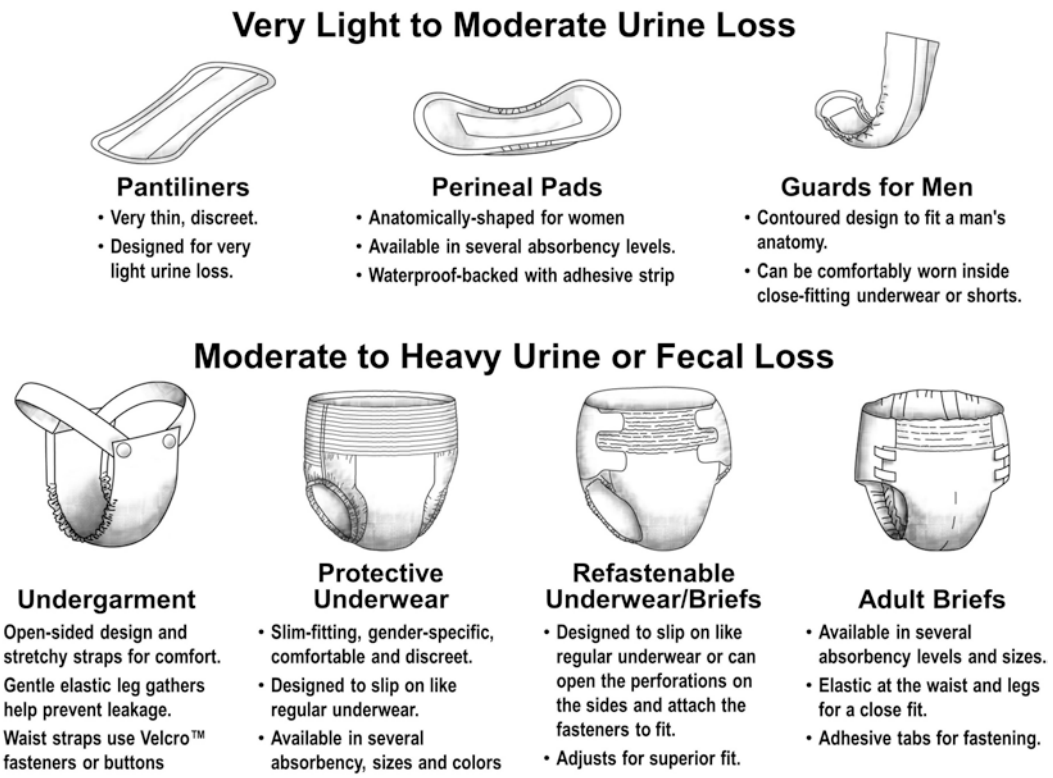

Fig. 6.1 Types of products for incontinence by absorbency level—Courtesy of Diane Newman

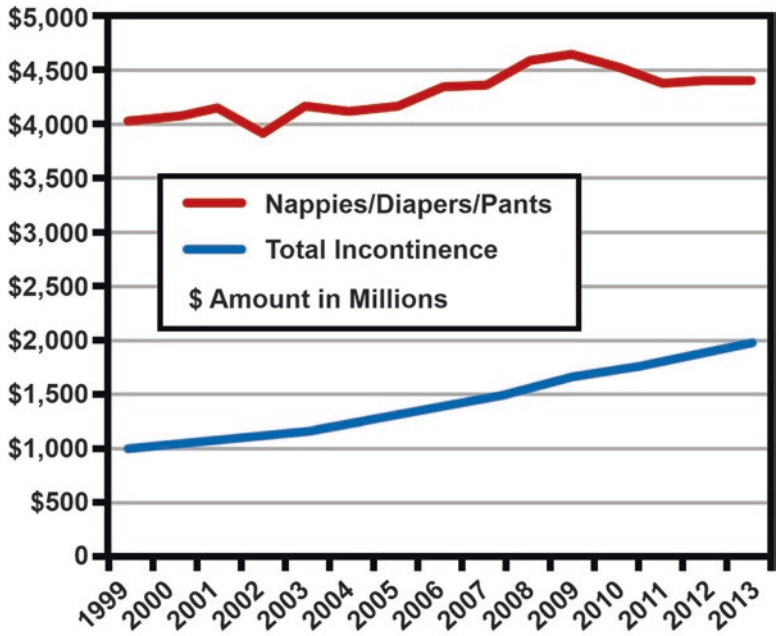

Chart 6.1 Adult absorbent product growth is outpacing baby products – Source Consumer Edge Research, Eurometer International [2]

incontinence, or in conjunction with other therapies, both medical and surgical. Due to the social stigma associated with incontinence in older individuals, absorbent products for incontinence are valued for their ability to protect against noticeable odors and visible signs of leakage, including soiling of clothing or other surfaces.

Prevalence

According to the Urology Care Foundation (http://www.urologyhealth.org/), as many as 1 in 3 adults experience bladder control issues. The statistics show that over 80% of those experiencing UI are women and the majority of cases are related to pregnancy and childbirth. The rise in prevalence can also be traced to the growing health conditions of obesity and diabetes, and the aging process.

The actual prevalence of absorbent product use for UI and FI is not known. In the acute care setting, hospital staff, particularly nurses, tend to use incontinence all-in-one briefs in patients whose condition may not necessarily require such a bladder management approach [3, 4]. Zisberg [5] conducted a study in five medical acute-care units (900 beds) in a teaching hospital in Israel to identify the incidence of in-hospital incontinence adult brief use, as compared to other products (e.g., urinals, bedside commodes, self-toileting). Fourteen percent (65/465) of older adults admitted to these units (66% females, 34% males) were provided incontinence briefs upon admission, despite the fact that all study participants reported that they were able to control their bladder. Commodes and urinals (38/465) were rarely used by female patients (30% females versus 70% males). Mobility, or lack thereof, was a predictor of incontinence all-in-one brief use.

The demand for products for adult incontinence products in the US is forecasted to rise over 48% through 2020, while baby diaper sales will only grow roughly 2.6% to 3% during the same time period (Bloomberg Businessweek) (see Chart 6.2).

Product Types and Categories

An absorbent product for incontinence should be chosen for or by the individual based on the quantity of urine leakage, the style, and the user's ability to apply the product. Absorbent properties and capabilities should be considered. The right absorbency level should be chosen based on the individual's needs, to ensure that skin exposure to urine and feces is minimized. Table 6.1 shows types of bodyworn absorbent products available for incontinence care noting absorbency. These product categories vary by their intended audience, functional design, and their overall capacity for protection [6]. As previously mentioned, there are two main types of absorbent products: reusable and disposable.

Reusable or *woven (washable) products* are composed primarily of absorbent natural and synthetic fabrics; therefore, they do not have the technological ability to keep wetness from the skin's surface or are they able to absorb multiple voids or incontinence episodes. These products are made from absorbent woven materials that can be laundered and re-utilized several times [7] (see Fig. 6.2). Many are homemade, made by the patient and/or

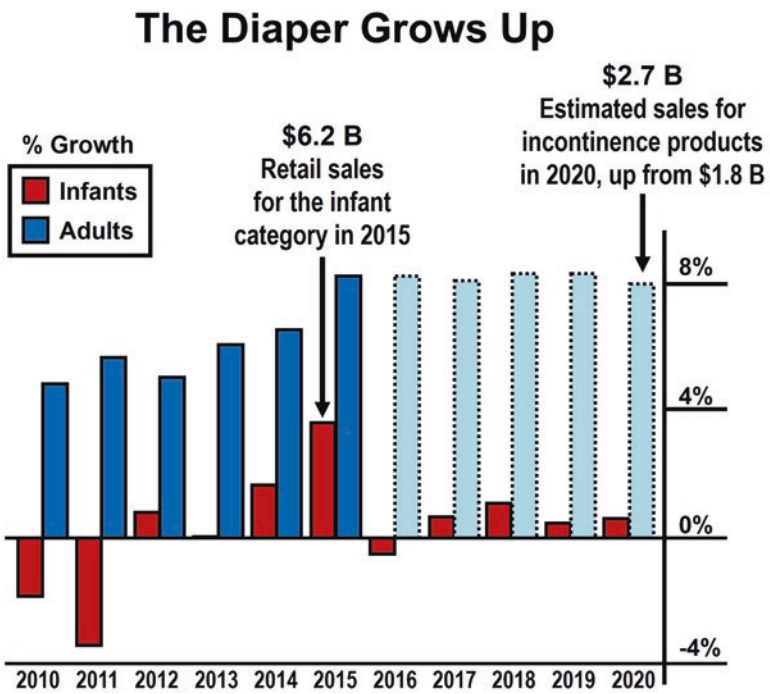

Chart 6.2 Sales of adult incontinence products are forecasted to rise 48% compared to baby diaper sales which are expected to only increase by only 2.6%. According to Bloomberg Businessweek, "As birthrates fall and life spans lengthen, the companies (Kimberly Clark, Proctor & Gamble) figure there's plenty of room for expansion, because babies grow out of diapers, but incontinent adults usually don't" (http://www.bloomberg.com/news/articles/2016-02-11/the-adult-diaper-market-is-about-to-take-off) [1]

caregiver and may include terry cloth (e.g. washcloth), safety pins, and plastic or vinyl pant). Although washable absorbent products are increasingly viewed as being environmentally friendly, a 2008 United Kingdom report on baby diapers (called "nappies") concluded that there was no significant difference in environmental impact between disposables and home or commercial laundered products, although the types of impacts did vary [8]. Typically, the average child used disposable diapers for an average of only two and a half years. Adults with UI tend to use these products for a longer period of time.

Common designs for these products include all-in-one briefs, or diaper-style products that have an integrated absorbent pad and fit close to the body to absorb leakage (see Fig. 6.3). There are also underpad styles that resemble a sheet or pad and rest on a support surface such as a chair (chair pad) or bed (bedpad) to provide protection and absorption. A waterproof backing on one side protects the support surface from wetness and odors.

The performance of most reusable products for incontinence is generally poor, particularly for preventing overflow leakage, when compared to disposable products. The materials composing these products are not effective in wicking moisture (pulling fluid away from the skin) and, therefore, are not indicated for multiple voids or incontinent episodes. They must be changed often, especially after a void or incontinent episode or there is a risk that moisture will sit against the skin. Their inability to effectively wick moisture away from the skin can impair skin health if not closely monitored [9]. When an individual's skin is left with an underpad resting under the body open to air, the urine and feces are not properly contained. Without the wicking action of a close-fitting absorbent product, positioned close to the perineum, urine leakage may run into the folds of the skin. Prolonged exposure to urine and feces in the skin creases, and on perineal surfaces, can lead to discomfort, skin irritation, maceration, and eventual skin breakdown. Also, when considering the use of an underpad for sole use (e.g., without a bodyworn product) the patient will need to be naked below the waist, so consultation and patient approval should be obtained [10] to help uphold their individualized choice and dignity. Reusable products are not recommended for persons with FI because of stool staining in the materials.

Disposable or non-woven products contain levels of pulp-derived fluff and SAPs to wick urine into the product for containment, minimizing wetness against the skin thus allowing for the absorbency of multiple voids or UI episodes into the product while keeping the skin surface dry. The basic technology of disposable absorbent products for incontinence derives from baby diapers [11, 12], with design and additional features specifically developed and adapted for the needs of adults. The fluid absorption capacity of these products reflects the larger urinary volumes of adults. Distinct features, such as the outer cover materials, are selected to avoid rustling noises. The anatomical product shapes, for example, are also designed for the optimal fit and comfort of adults wearers [13, 14].

Although features vary depending on the quality and intended product use, certain standards are common to

Table 6.1 Most commonly used absorbent products for incontinence and usage consideration

Product/Device	Description	Usage Considerations
Pantiliners, pads, perineal pads	• Anatomically-shaped for female genitalia • Available in a variety of sizes (e.g., thin to ultra-heavy) • Attach to the underwear or panties with an adhesive strip on the back • Have side gathers for a comfortable fit • Allow for easy removal when urinating	• Use in individuals with slight or light incontinence (e.g., stress UI) • Discrete • Held in place by close-fitting underwear or purpose-made knit or mesh pants • Some are designed with a wider back for larger volumes of leakage • Heavy pads can be a good choice for FI because it is more cost-effective to change the pad often
Inserts, booster pads, shields, microliners	• Many have an adhesive strip on the back to help secure them • Shape, thickness and absorbency differs between available products • Do not have waterproof-backing	• Washable inserts are available but not favored by most individuals • Can be used in combination with other absorbent products • Provides added protection for containing leakage as it can be easily removed and discarded when saturated
Male guards, drip collection pouches	• Anatomically-shaped for male genitals with wider part in front • Have adhesive strip on back to attach to close-fitting underwear • Sock-like drip collection pouches are designed to hold the penis • Generally hold 250 mLs	• Use in men with slight or light incontinence (e.g. stress UI) • Helpful for men with incontinence post prostate surgery • Penis is placed in the drip collector and pouch pad absorbs urine leakage
Protective underwear, (may be referred to as "pull-ups")	• Elasticated absorbent "underwear" pulled on much like regular underwear to provide a close fit • Closely resemble regular male-brief underwear and female panty-style underwear • Waterproof backing • Some may have refastenable tabs • SAP core is either in the crotch or spread throughout the product	• Use in individuals with moderate to heavy leakage (urgency UI) • Have a "natural feel" • Very popular product; some available with colored backsheets and with designs to more closely resemble cloth underwear • Community-dwelling women report preferring this design over others • Most effective product style for those with cognitive impairment • Disadvantage is that clothes (pants) must be fully removed to change this product when wet. But some designs have side seams can be torn away for easy removal • High-quality high-absorbency products will feature a wetness indicator that changes color when the product is wet to signal the amount of absorbency utilized and/or the need to change the product
Adult briefs (Adult diapers) -"all-in-one" product	• "Diaper-like" products that have elasticized waist and legs and self-adhesive tabs that are resealable • Some have been modified to a "T-shape" that is first fastened around the waist and the front is pulled into position and secured • Good at containing large amounts of urine leakage (heavy voids, full voids) • May deter the person from self-toileting as they are difficult to remove and re-apply	• Use in individuals with moderate or heavy incontinence (urgency UI, UI without awareness) • Use for patient with double incontinence, both FI and UI • Easy application; • T-shaped product can be applied while person is standing • Normally have a "wetness indicator" that changes color when the product is wet to signal the amount of absorbency utilized and/or the need to change the product

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most products. These include products manufactured to be latex-free so as to minimize or avoid any potential skin sensitivities. All disposable products contain a moisture-proof lining that prevents liquid from escaping the product. In the past, products have offered only a plastic backsheet that was mostly uncomfortable for the wearer and potentially embarrassing. The products could rustle and emit noise as the person moved normally. Today, many products feature a soft, textile-like waterproof backsheet that is much more comfortable and feels more like a normal garment. Wearers prefer the cloth-like backsheet, which makes the product noiseless and helps promote wearer dignity and privacy.

The use of SAP technology is also now a standard in absorbent product technology; however, the amount of SAP granules utilized in the product will vary depending on the

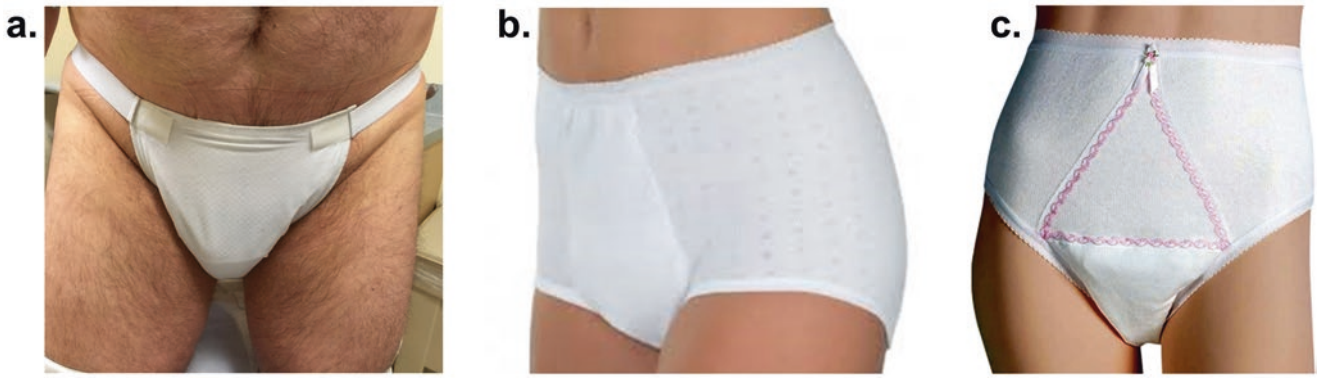

Fig. 6.2 Washable woven absorbent products (**a**) Undergarment with belt and Velcro™ fasteners (**b–c**) Underwear with integrated pad

Fig. 6.3 Washable and reusable "Diaper-style" all-in-one products

quality of the product manufacturing, and the intended product. Most incontinence experts recommend the use of products containing SAP because, when utilized properly, this technology may have a significant impact in preventing complications such as incontinence-associated dermatitis (IAD) and subsequent development of pressure injury (see Chap. 8). Most of the current high-quality products on the market (e.g., Abena®, Attends®, TENA®) are designed to be skin-friendly. This means they provide a surface area against the individual's perineum that collects and transmits moisture from the acquisition layer to the inner core of the product that contains the SAP, which locks in the moisture. Absorbent cores that contain SAP will be more effective and contain more urine than a core containing just fluff pulp to absorb moisture.

Well-engineered, innovative absorbent products for moderate to heavy incontinence have two layers to properly function and will contain both bladder leakage and stool. These products have a surface area (generally an acquisition layer) that absorbs and collects the urine, drawing urine in and transmitting it to the lower SAP inner core. The layer closest to the skin is designed to wick moisture and disperse the urine along the inner absorbent layer, to maintain a surface that is as dry as possible against the skin. Four minutes after an incontinence episode, 80% of the inner core of SAP will be dry, though it takes an additional four minutes to reach equilibrium. The inner core promotes urine distribution throughout the entire product, facilitating absorption capacity while functioning to prevent urine leakage and odor. In addition to facilitating absorption capacity, this inner core allows the urine to spread throughout the entire layer, locking it into superabsorbent granules as a gel. The product's design features a combination of absorbent cores or layers which work in tandem to provide the total absorptive capacity for the product. Newer products may have a third layer, called the superabsorbent layer (see Fig. 6.4).

The amount of SAP and fluff utilized in a product will determine the total capacity that it can absorb. Higher quality product lines will generally contain more absorbent materials overall. The industry standard measure of a product's total performance when fully saturated is termed the ISO Absorbency Rothwell method. Additional product parameters that indicate the performance of a product include the absorption speed, absorption under direct pressure, and re-wet testing. The combination of all performance factors will determine the most effective product.

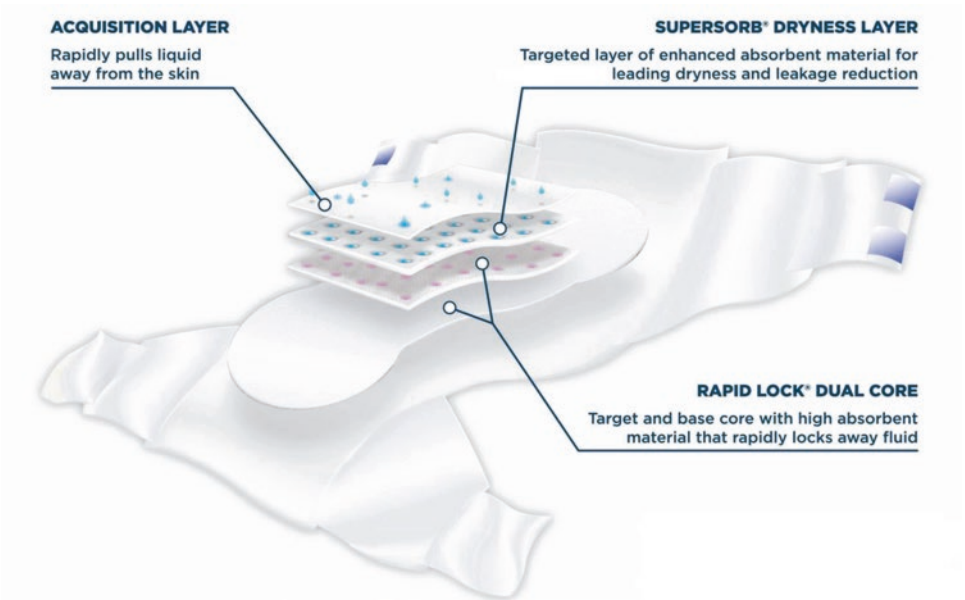

Fig. 6.4 Advanced DermaDry/Supersorb Technology—(Attends®)—Courtesy of Domtar Personal Care

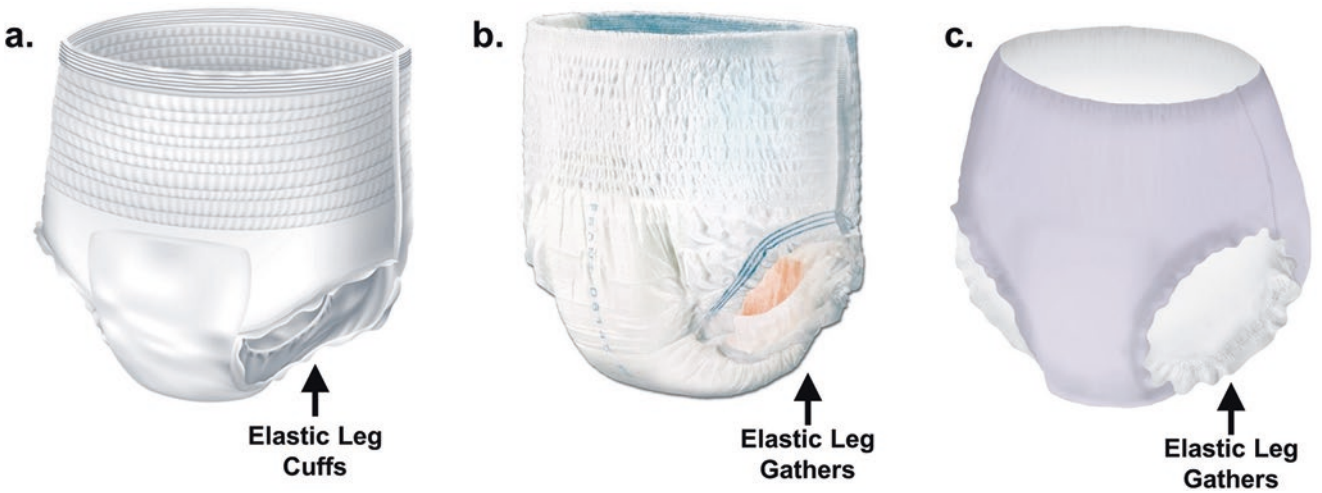

Fig. 6.5 Protective underwear. (**a**) Elastic leg cuffs (Attends®)—Courtesy of Domtar Personal Care. (**b**) Elastic leg gathers (Tranquility®)—Courtesy of Principle Business Enterprises. (**c**) Elastic leg cuffs (Prevail)—Courtesy of First Quality

The absorption speed of a product is known as its acquisition speed and is often measured in tandem with the testing for re-wet. Re-wet represents how dry a product will stay during normal use, or how wet the surface of the product will stay when subjected to pressure (i.e., the pressure of the body during normal wear against the product surface). Because fluid and wetness against the skin is negative for wearers and for skin health, an effective product design in tandem with the strategic use of SAP can influence the feeling of dryness against the skin and, in turn, user satisfaction. Re-wet values determined in a laboratory will not be the same as the values determined in use, due to the natural factors of product compression and handling during actual use. The temperature of the fluid and of the individual will also affect the absorption rate and re-wet performance.

Full product performance is truly determined by the perceptions and feeling of dryness and comfort by the individual wearer and/or individual utilizing the product for incontinence protection. When evaluating absorbent product materials for quality and performance, the accumulative array of features and construction should be considered, rather than claimed absorbent capacity. Higher-quality products will not only contain quality materials and claim a high absorbent capacity, but will also be constructed to fit comfortably

against the body and offer additional features that work in combination for improved performance and wearer comfort. These features include areas of SAP concentration, also known as zoned SAP, placed strategically in the product core to improve acquisition speed, re-wet performance, and odor control. Other features that help effectively contain leakage include longitudinal leg cuffs and elastics (see Fig. 6.5) that hug the curves of the body and act as additional guards against leakage. It is important to check the construction of the leg cuffs to ensure their viability and effective functioning while remaining comfortable.

Technological Advances in Absorbency

The use of SAP in adult incontinence products began in the 1970s. This petroleum-derived material is impregnated into the product core as a granule that swells as it absorbs and locks in moisture (see Fig. 6.6). Current SAP technology allows for very effective absorption. Presently, SAP granules can absorb up to 70 times their original weight in urine and swell to an average particle size of 1–2 mm.

When designing the absorbent products, manufacturers decide where to position the SAP within the absorbent core for effective wicking of moisture and product performance. The SAP is concentrated in what is known as the "strike zone" in the product, which denotes where the void is likely to immediately reach the product as it leaves the body (see Fig. 6.7). Depending on the product and its intended user, manufacturers will develop targeted zones with areas of more concentrated SAP granules to help facilitate rapid absorption. For example, products intended for men will have their strike zone positioned to specifically work with the needs and natural voiding function of the male anatomy and will be positioned more in the front of the product. The strike zone for women will relate to female anatomy and be targeted to ensure comfort and quick absorption. The outside of the product will usually have a "wetness indicator" that changes color as urine transmits through the different layers (see Figs. 6.7 and 6.8). Besides the SAP, the pulp fibers within the product function to help to spread liquid quickly and efficiently around the entire absorbent core, for even absorption and more wearer comfort.

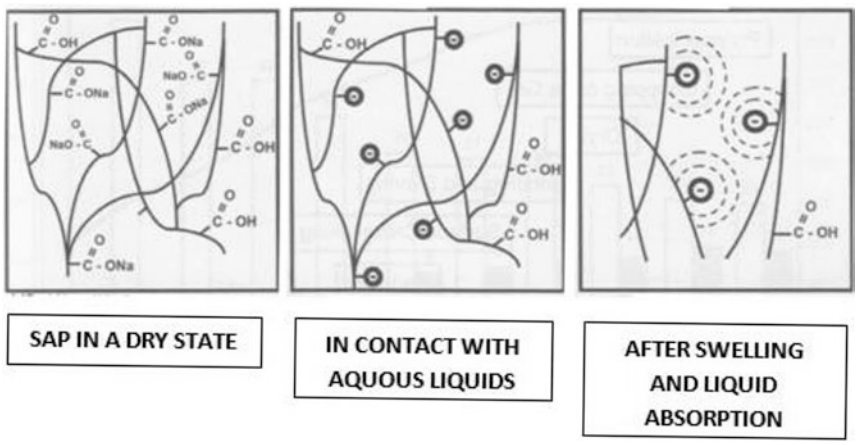

Fig. 6.6 Superabsorbent polymer (SAP) technology [15]

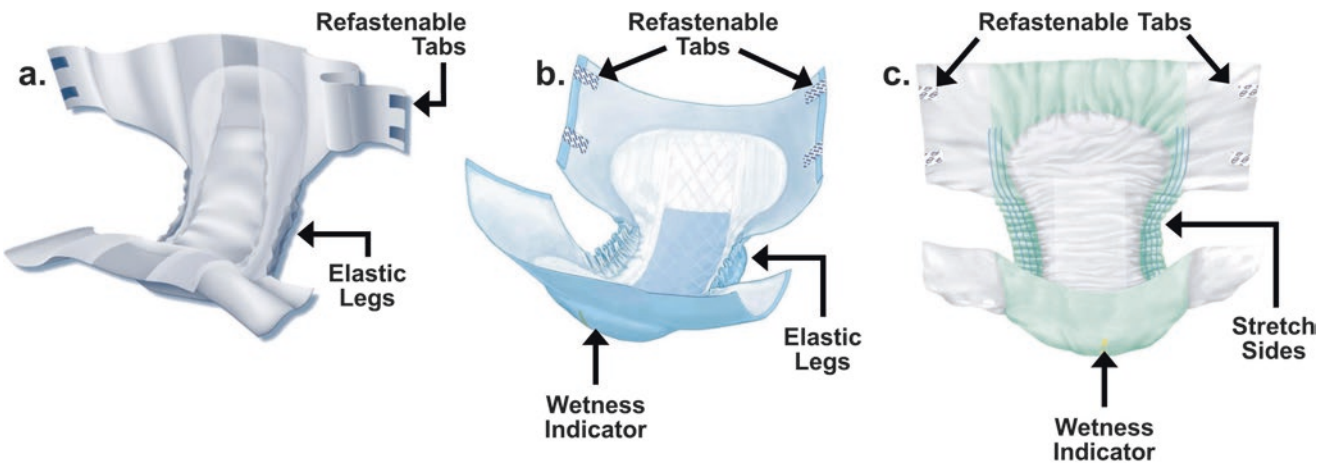

Fig. 6.7 Extra-absorbent breathable all-in-one briefs with external wetness indicators, elastic legs, and stretch sides

Fig. 6.8 (**a**) Abri-San special pad for FI (**b**) Abri-Flex protective underwear (**c**) Abri-Form premium (Abena®)—Courtesy of XP Medical

In higher-quality products, additional features are added to help minimize the risk of leakage, while promoting wearer comfort. Some products feature a top "acquisition" layer against the skin that facilitates more rapid absorption, while providing a dry surface against the skin. Other useful features include leg cuffs that fit into the groin area, helping to provide a comfortable and efficient barrier against leaking (see Fig. 6.5). These leg cuffs feature elastic that can help provide a more comfortable, secure fit against the body.

In addition to leakage protection, odor control is one of the most valued features for disposable bodyworn products. No matter how long the product is worn, the individual should feel comfortable, confident, and odor-free. If the products are worn for several hours or extended periods of time, and contain multiple voids, it is even more critical for the product to effectively control odor. Manufacturers employ varying systems in the designs of their products to promote superior odor control and wearer confidence. New odor neutralizing technology continues to be developed [16]. While the natural acidic level of the SAP material naturally makes it effective in controlling odors related to UI, other elements may be added to minimize odor and support wearer confidence.

Having an effective body-close fit is key for ensuring product performance, leakage protection and odor control. The most important consideration for the wearer is choosing the correct size. The wearer then must ensure that the product is applied properly to support a close fit. With pad products, correct application of the product in the undergarment is key. In all-in-one brief products, the ability to refasten and reposition the product closures without ripping or damaging the product is an important feature that ensures the product fits securely and functions properly. Refastenable tabs with Velcro™-like hook closures are seen as most effective in promoting ease of utilization (see Fig. 6.9) and application. Plastic-backed products are still common, but to help maximize skin comfort and health, the preferred high quality absorbent product designs feature a cloth-like backsheet. In addition to being more comfortable for the wearer due to the textile feel, this material is also known to allow for more "breathability," i.e., air flow against the skin. It is important to note that the use and claim

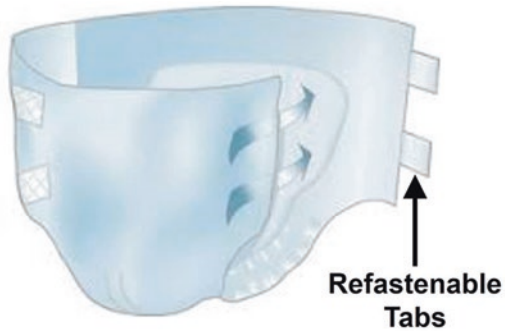

Fig. 6.9 Adult all-in-one brief with refastenable tabs

of "breathable side panels" in all-in-one brief and diaper-style products has been widely promoted in the industry, but is misunderstood or misrepresented. Therefore, it is important to ask exactly where the product is considered breathable, and to check the construction of the material in any area designated as "breathable," to ensure that actual skin benefits can be realized by the wearer. Only a small number of advanced products exist that employ a truly breathable backsheet in their products (i.e., the Abena® brand as shown in Fig. 6.8 is one example) with microporous openings that allow water vapor to pass to the outside of the product and offer air permeability while still effectively locking in moisture and odors. Comfort and skin health as it relates to breathability in products is directly related to air permeability and the water vapor transmission rate. Thus, breathability is valuable in promoting the highest levels of comfort and dignity for the wearer.

Product Functional Design and Application

Absorbent disposable products for incontinence feature a variety of designs, sizes, absorbency levels, and functional attributes to meet the needs of the wearer and to maintain the highest possible quality of life.

- *Guards and drip collection pouches* are designed for men to fit very close to the penis and contain urine drips

and slight leakage. Both utilize an adhesive strip, are "cup-like," and are effective when worn with close-fitting underwear. This style is not indicated for FI. The older of the two styles, the drip collection pouch (see Fig. 6.10) is an absorbent pouch design that allows the penis to sit in the well of the pouch and contain leakage. This style was formerly only indicated for very light leakage, because it did not contain SAPs. Newer male guard designs contain SAPs and can absorb moderate bladder leakage of up to 250 cubic centimetre (cc) before reaching capacity (see Fig. 6.11). The guard technology is the more recent of the two designs and resembles a male protective cup used in sports gear. It is made to fit similarly against the body with a discreet profile.

- *Pantiliners*, *micro-liners*, *and perineal pads for light to moderate incontinence* vary in size and shape depending on their intended coverage and absorbency, and provide a wide range of discreet protection levels from very light to heavy bladder leakage (see Fig. 6.12). These pads utilize an adhesive strip to adhere to normal close-fitting underwear (female underwear or male briefs). They are easily applied and preferred by many for portability and discretion under clothing, which helps with maintaining dignity and normalizing the condition of incontinence. This style of perineal pad is anatomically designed for women and similar to feminine hygiene products. It is important to note, however, that incontinence pads are designed to absorb urine and feminine hygiene products are designed to absorb menstrual blood. Therefore, feminine hygiene products will not effectively contain urine leakage. It has been estimated that 25% of menstruating women with slight to moderate UI use feminine hygiene products to contain urine loss. This may contribute to the normalization of UI by many women who are used to wearing pads. However, these products are utilized often by men as well for their ease of use and application, and also because many are not aware that there are other options available that are anatomically designed for men. This product style is not indicated for FI.
- *Inserts*, also known as *liners* or *booster* pads, are placed inside woven or nonwoven products to extend the life of the original or main product (see Fig. 6.13). Individuals discard the pad once it becomes saturated.
- Different styles of "*butterfly*" *shaped thin pads* are available for fecal staining to light FI (see Fig. 6.14). Their design allows for simple application between the gluteal muscle and on the anus with the use of adhesive and once applied, the pad should stay in place with normal activity. This style protects against fecal staining and is indicated for absorption of light fecal leakage, commonly associated with diarrhea, incontinence, hemorrhoids, or surgery.
- *Undergarments* for incontinence care are commonly referred to as *belted undergarments*, due to their design utilizing a belt to hold the product in place against the

Fig. 6.10 Male drip collector pouch—Courtesy of Coloplast Corp.

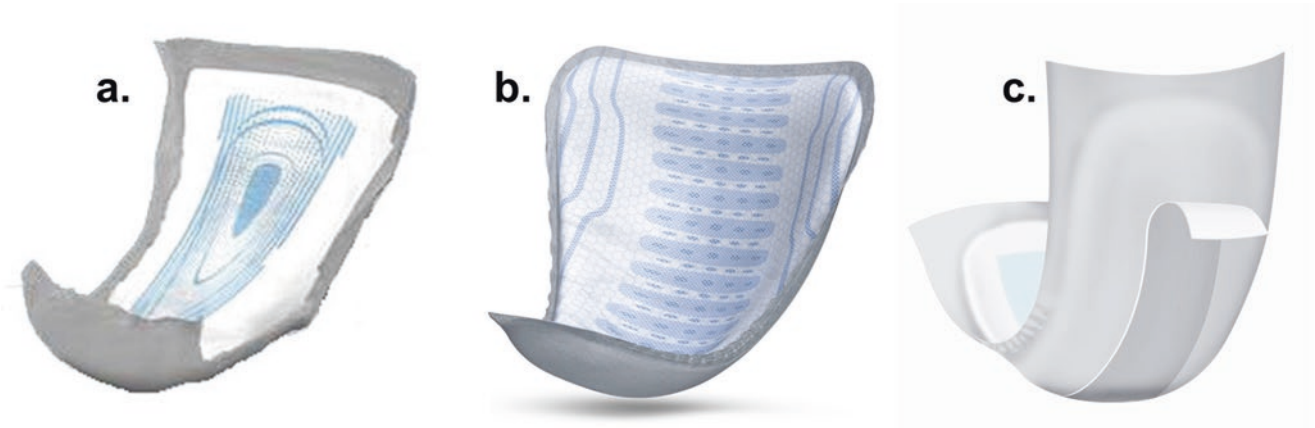

Fig. 6.11 Male guard pads with adhesive strip on back. (**a**) Depend®—Courtesy of Kimberly Clark. (**b**) TENA®—Courtesy of Essity (formerly SCA Hygiene Products). (**c**) Prevail® with adhesive strip on back of pad—Courtesy of First Quality

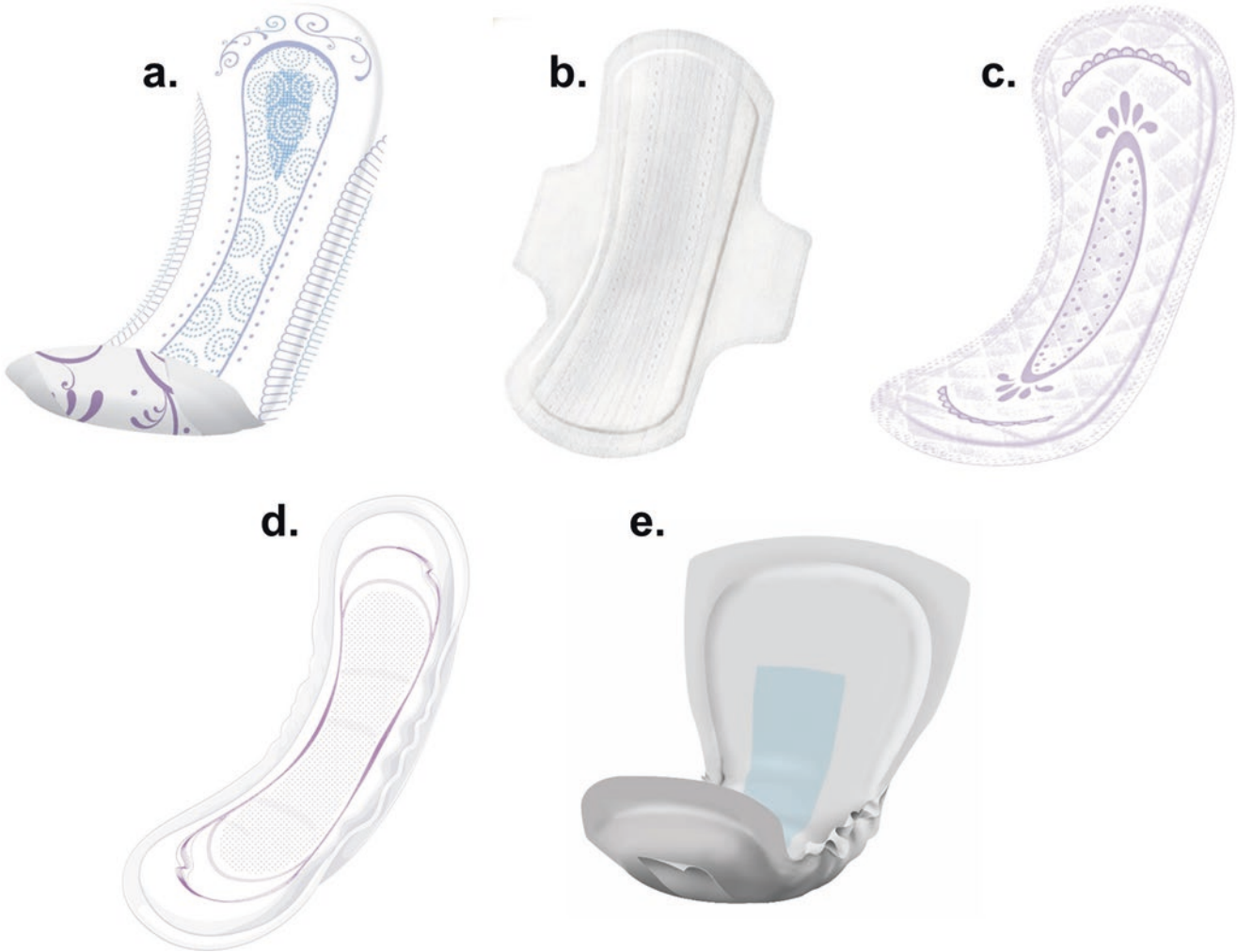

Fig. 6.12 Anatomically shaped pads with adhesive strip on back. (**a**) Maximum pad (Poise by Depend®)—Courtesy of Kimberly Clark. (**b**) Ultra-thin pads with wings (TENA® Serenity)—Courtesy of Essity (formerly SCA Hygiene Products). (**c**) Discreet very light long length liners (Always®)—Courtesy of Proctor and Gamble. (**d**) InstaDRY heavy long pads (TENA® Serenity)—Courtesy of Essity (formerly SCA Hygiene Products). (**e**) Perineal pad elastic leg cuffs (Attends®)—Courtesy of Domtar Personal Care

perineum. This design fits discreetly under clothing and consists of an absorbent pad with areas to connect the belt on the front and back of the product. The belt may be connected by buttons, as in the original design, or a more modern hook and loop fastener or Velcro™ (see Fig. 6.15). This style may be preferred due to the security of the application and the absorbency provided. The belt application may also be easier to apply for those individuals with limited mobility, and the thin belt also provides a cooler feeling because the skin is open and uncovered on the sides and hips. Additionally, this style provides more flexibility for a busy or active individual, since the product can be removed or changed without having to take off pants and shoes. However, the design is not ideal for restless sleepers or those that tend to lay on their sides. In situations where increased absorbency is needed, some utilize an additional insert or "booster" pad.

- *Washable pants and disposable pad systems are two-piece combinations of products* that provide protection from light to heavy bladder and/or bowel incontinence. This style is designed to be applied and to function as normal underwear with a pad insert. The pad is generally designed to be much larger than pantiliners or light incontinence pads and can provide a wider range of coverage, including very heavy bladder and fecal leakage. A heavy pad product developed with specialized pockets designed to effectively capture fecal leakage (i.e., the Abena Special Pad) is indicated for persons with FI and can be a very cost-effective option when the pad needs to be changed often, as in the instance of diarrhea outbreaks. The heavy disposable protection pads often feature a wetness indicator that alert the wearer or caregiver when the pad should be changed. While many of these pad styles feature an adhesive band, some of the larger

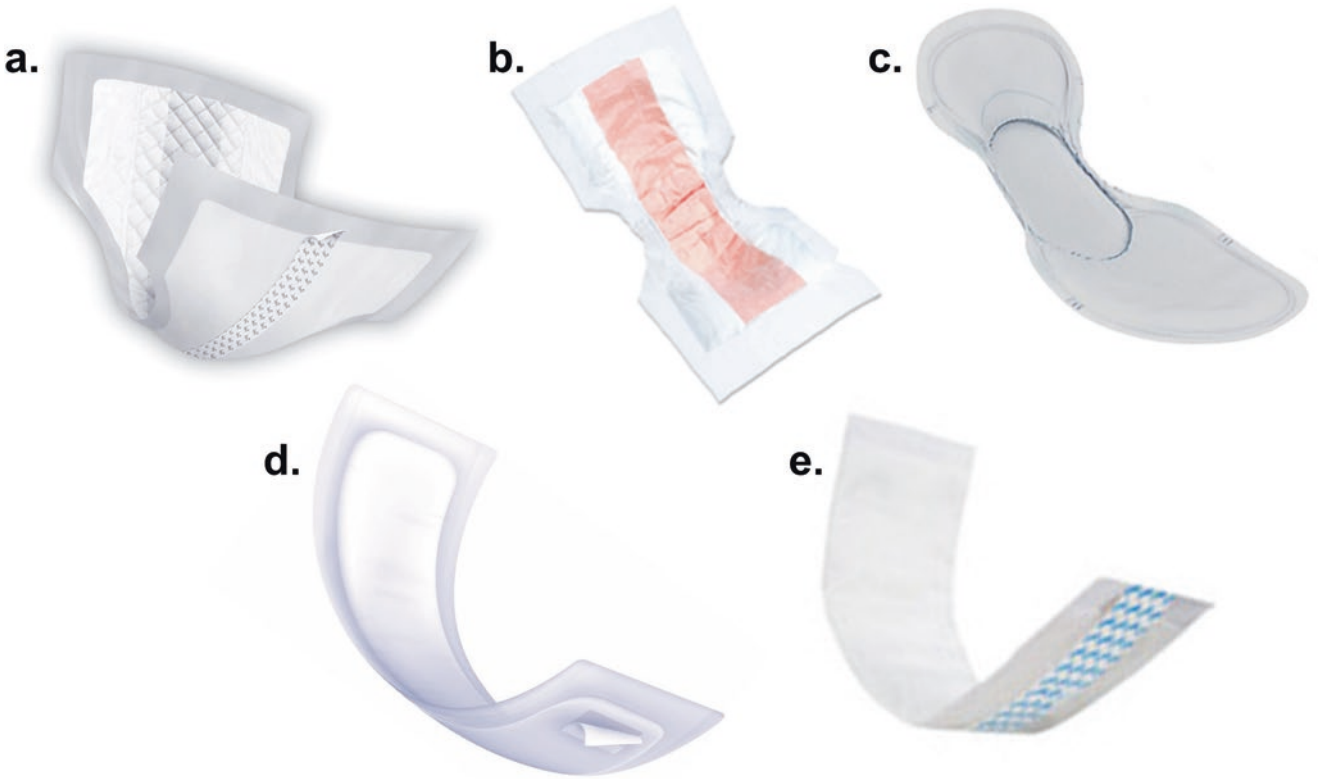

Fig. 6.13 Insert, booster, or liner pads

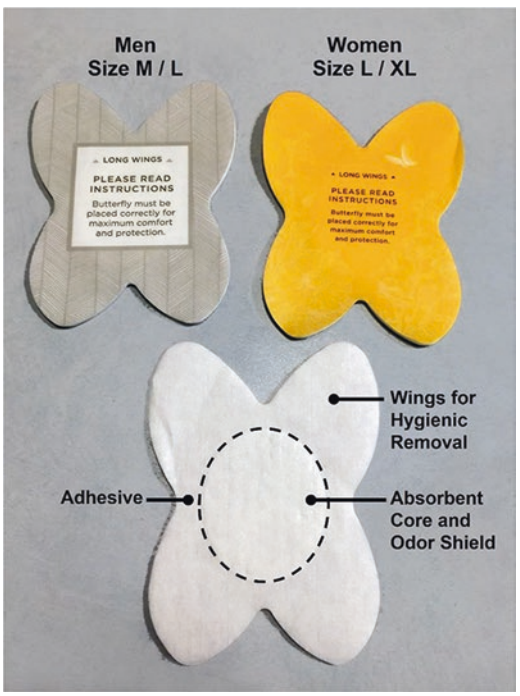

Fig. 6.14 Pads for FI (Butterfly)—Courtesy of Domtar Personal Care

pads do not. The pant is pulled-up to hold the pad in place and to fit like normal close-fitting underwear. Washable and reusable pants come in a variety of sizes and stretch to fit the body comfortably while holding the absorbent product in place. Washable pants may be in a traditional knit style or a cooler mesh style that allows for more air flow against the skin (see Fig. 6.16). These pants can be laundered and used multiple times before discarding. This style may be ideal to help promote dignity for those with incontinence requiring heavy protection that do not wish to wear a brief or diaper-type product. Washable pants can also be a great option for those that require heavy protection but want the coolest possible product style; in this case, a heavy pad with a mesh-style reusable pant is effective. The flexibility of the pad and pant style makes this system useful for larger/taller individuals or those requiring bariatric care, since pant sizes range up to 5 XL.

- *Protective underwear for moderate to heavy bladder leakage and/or light bowel leakage* are the most popular and best-selling product category with consumers (see Fig. 6.5). They feature a simple to apply pull-on style that resembles and is worn like regular cloth underwear, for a discreet fit and maximum dignity. This style is widely pre-

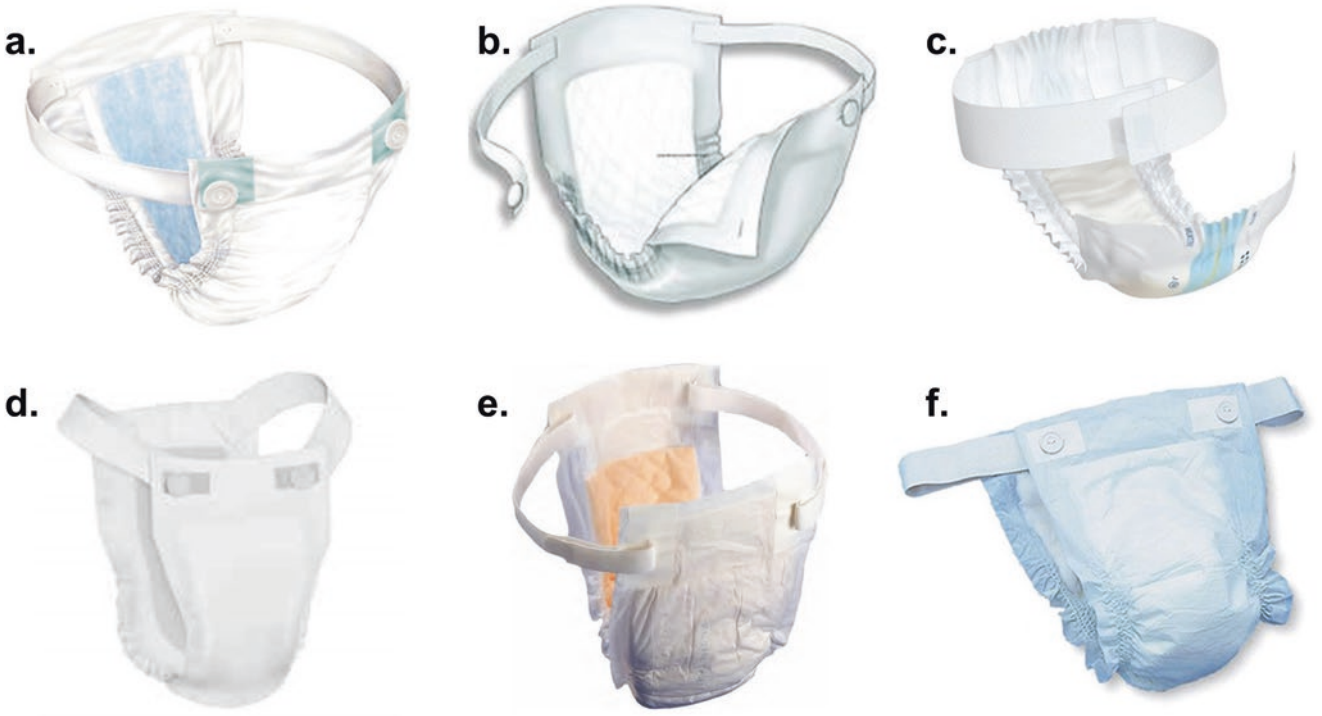

Fig. 6.15 Undergarments. (**a**) Undergarment with reusable buttonhole belt straps (TENA®)—Courtesy of Essity (formerly SCA Hygiene Products). (**b**) Belted super absorbency undergarment with straps (MaxiCare)—Courtesy of Covidien Kendall. (**c**) Flex incontinence briefs (TENA®)—Courtesy of Essity (formerly SCA Hygiene Products). (**d**) Belted shield with reusable buttonhole belt straps (Prevail®)—Courtesy of First Quality. (**e**) Belted undergarments-Tranquility®—Courtesy of principle business enterprise (**f**) Belted undergarment with buttons—Courtesy of Medline

ferred over adult diaper products for its dignified design that seamlessly fits into a normal lifestyle, while providing a high level of coverage through an absorbent core and moisture-proof lining. The comfortable fit is accomplished through elastic bands constructed around the waist for a custom fit. Many high quality disposable protective underwear products feature standing gathers and leg cuffs to help contain leaks. To meet specific functional needs, a wide variety of absorbencies are available, from moderate to very heavy and overnight product styles. Recent styles include gender-specific technology, with zoned SAP, and cloth-like, innovative features to maximize the comfort and dignity for men and women. The popularity of the protective underwear design has increased demand for larger sizes, and many manufacturers now offer XXL sizes to fit up to 80″ waists and adjustable styles with hook and loop closures that offer a customizable fit. These products are more similar to cloth underwear and are now available in colors (see Figs. 6.17 and 6.18) to increase attractiveness to men and women. Active individuals often prefer these products for their added security, and they can be worn at night for additional security by those who wear a pad during the day. In addition to disposable styles, reusable absorbent styles are also available. Both disposable and reusable specialty styles that can be worn while swimming. In clinical care settings, this style has been found to be effective in supporting individuals with cognitive impairment, such as Alzheimer's and dementia who have UI.

- *Adult briefs (diaper-style or all-in-one products) for moderate to heavy bladder and/or bowel incontinence* provide the highest level of coverage and protection. Aside from traditional baby products, absorbent all-in-one briefs are tab-style diapers that are available in sizes to support youth through adulthood (see Fig. 6.19). These are applied to fit close to the body and provide maximum protection. Most are designed to be refastenable with either tape tabs on a refastenable designated zone on the plastic backsheet, or hook and loop style tabs that allow for multiple refastening on cloth-like non-woven backsheets. All disposable briefs feature a moisture-proof lining made from either the traditional plastic-backed material or the softer non-woven cloth-like material. Many customers prefer the cloth-like material, because it is more discreet and effective in reducing rustling or unintended noise while walking. All-in-one style products are preferred and most effective in individuals experiencing heavy or continuous bladder leakage and/or bowel incontinence. They are commonly used in acute care, long-term care, and hospice settings. The close-fitting style provides maximum protection, coverage, and odor control, which makes it a preferred

Fig. 6.16 Pad-pant disposable systems. (**a**) Day pad held in place by pant or mesh pant—Courtesy of Essity (formerly SCA Personal Hygiene). (**b**) Mesh pants in various size (Comfort pants) (TENA®)—Courtesy of Essity (formerly SCA Personal Hygiene). (**c**) Reusable seamless, stretchable material (Comfort pants)—Courtesy of Essity (formerly SCA Personal Hygiene). (**d**) Mesh underwear with inserted pad (TENA®)—Courtesy of Essity (formerly SCA Personal Hygiene)

Fig. 6.17 Gender-specific disposable protective underwear for men. (**a**) Silhouette (Depend®)—Courtesy of Kimberly-Clark. (**b**) Fit-flex (Depend®)—Courtesy of Kimberly-Clark. (**c**) Super Plus (TENA®)—Courtesy of Essity (formerly SCA Personal Hygiene)

Fig. 6.18 Gender-specific disposable protective underwear for women. (**a**) Silhouette (Depend®)—Courtesy of Kimberly-Clark. (**b**) Silhouette active fit moderate absorbency (Depend®)—Courtesy of Kimberly-Clark. (**c**) Night-defense maximum absorbency (Depend®)—Courtesy of Kimberly-Clark. (**d**) Protective underwear (TENA®)—Courtesy of Essity (formerly SCA Personal Hygiene)

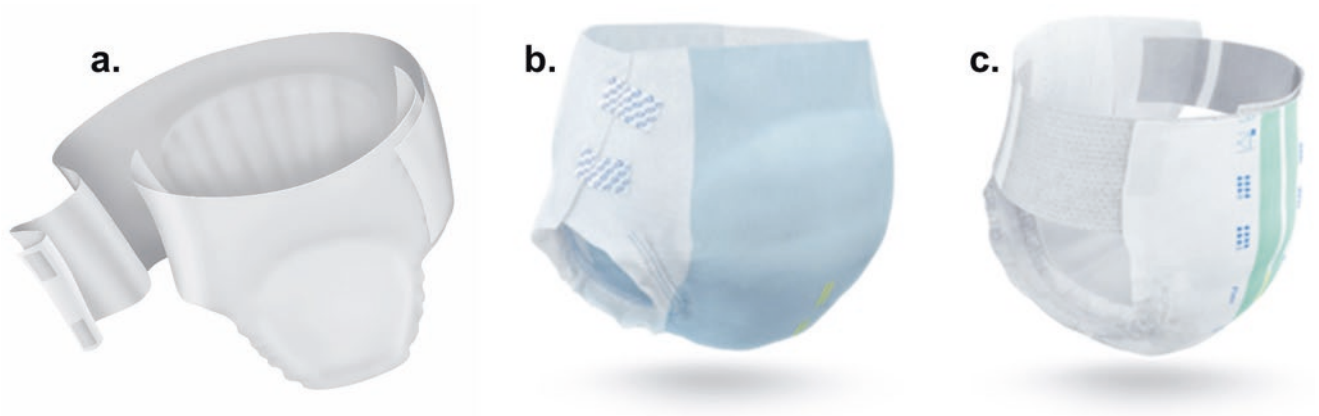

Fig. 6.19 Adult all-in-one briefs. (**a**) Bariatric brief—Courtesy of First Quality. (**b**) Adult brief (TENA®)—Courtesy of Essity (formerly SCA Personal Hygiene). (**c**) Belted brief (TENA® Flex)—Courtesy of Essity (formerly SCA Personal Hygiene)

style for nighttime protection when heavier coverage is required. Some brief products are designed to have a wider back to offer more protection and should be utilized at nighttime when there is an increase in bladder volume. For this reason, some individuals utilize a protective underwear product during the day and then wear a brief at night to provide full coverage and confidence, while the higher absorbent properties keep the skin feeling dry and promote a more restful sleep.

Demand for the brief-style of absorbent incontinence product has grown significantly over the past 20 years, due to their varied applications in clinical, health care, assisted living, home care, and hospice settings. The demand has driven product development and innovations positively in the product category. Innovations focus on improving product utilization and wearer experience. Utilization improvements include improved core designs with strategic placement of SAP for better performance, which can lead to less product changes and an overall lower cost of care overall (known as lower cost-in-use). In higher quality absorbent lines, it is not uncommon to see product change rates of 3–4 times during a 24 hours (h) time period.

A few years ago, the advent of the so-called "breathable products" that help avoid complications of skin issues took the market by storm. Breathability is now a common, but often misleading, product feature. The need for easier application and improved fit drove the evolution of belted briefs and briefs featuring stretchy side panels. The need for improved sleep hygiene and products promoting more restful, uninterrupted sleep has expanded the development of nighttime and extended-wear brief products. The popularity and demand for these products is expected to rise as clinical studies demonstrate multiple related benefits for the wearers. Other technological innovations continue to evolve around wetness indicators and ways to monitor void volumes, sizes for bariatric patients, and product changes to allow for stretching (See Fig. 6.20). This technology is most applicable in extended care and clinical settings, where caregivers are required to monitor voiding patterns to develop effective care plans.

Underpads

In addition to bodyworn absorbent products for incontinence, there are products that are placed under the perineum and buttocks for absorbing urine. These are referred to as underpads or bedpads and can be either disposable or reusable.

These products are not worn against the body but rest on support surfaces to absorb and protect those surfaces against bladder and/or bowel leakage with a waterproof protective lining. Disposable underpads are also commonly called chux

Fig. 6.20 Disposable absorbent underpad, also known as "blue chux"

(see Fig. 6.20), as they are "chucked" out after use. A benefit of an underpad is the multiple layers used to prevent wetness from spreading to the mattress, furniture, wheelchairs, car seat, and so on. Over the past several years, underpads have also been commonly used to reposition the individual while in bed. For research purposes, these products have been used to estimate urine output in the clinical care setting [17]. When choosing a product, be sure to choose the correct size so it will adequately absorb the urine output. One best to practice is to allow up to 10 in. of additional space around the normal urine leakage zone to give the individual freedom to move or reposition themselves without risking leakage. Many individuals believe "bigger is better" when it comes to underpad selection, but in reality the product size should be chosen based on adequate coverage, with the best material construction for the individual's needs. For those that are more restless, underpads with wings are available that tuck under the mattress to stay securely in place. Positioning bands can also be attached to the bed and underpad to keep it from moving or bunching when the individual moves.

- *Cloth reusable underpads* are the original style of bed and chair protection. These are often used in tandem with another absorbent product to provide additional protection for support surfaces. Some prefer this product for its minimization of the number of disposable underpads purchased, and perception as a stronger and more durable option. When choosing a reusable product, one must consider its construction, materials and size in relation to the needs of the incontinent individual. In evaluating reusable underpads, consider the integrity of the moisture-proof barrier that is on the product. Vinyl barriers are more cost-effective generally, but are not constructed with a "breathable" material and may cause heat build-up while the individual is sleeping. These often take additional time to dry after being washed, which could affect utility bill costs and reuse. Products with urethane backings are more expensive, but also more durable and, therefore, last longer. Urethane causes less rustling and is more discreet. It is also considered "breathable" and allows for heat to escape, so the individual will sleep more comfortably without heat build-up. Finally, it will launder and dry

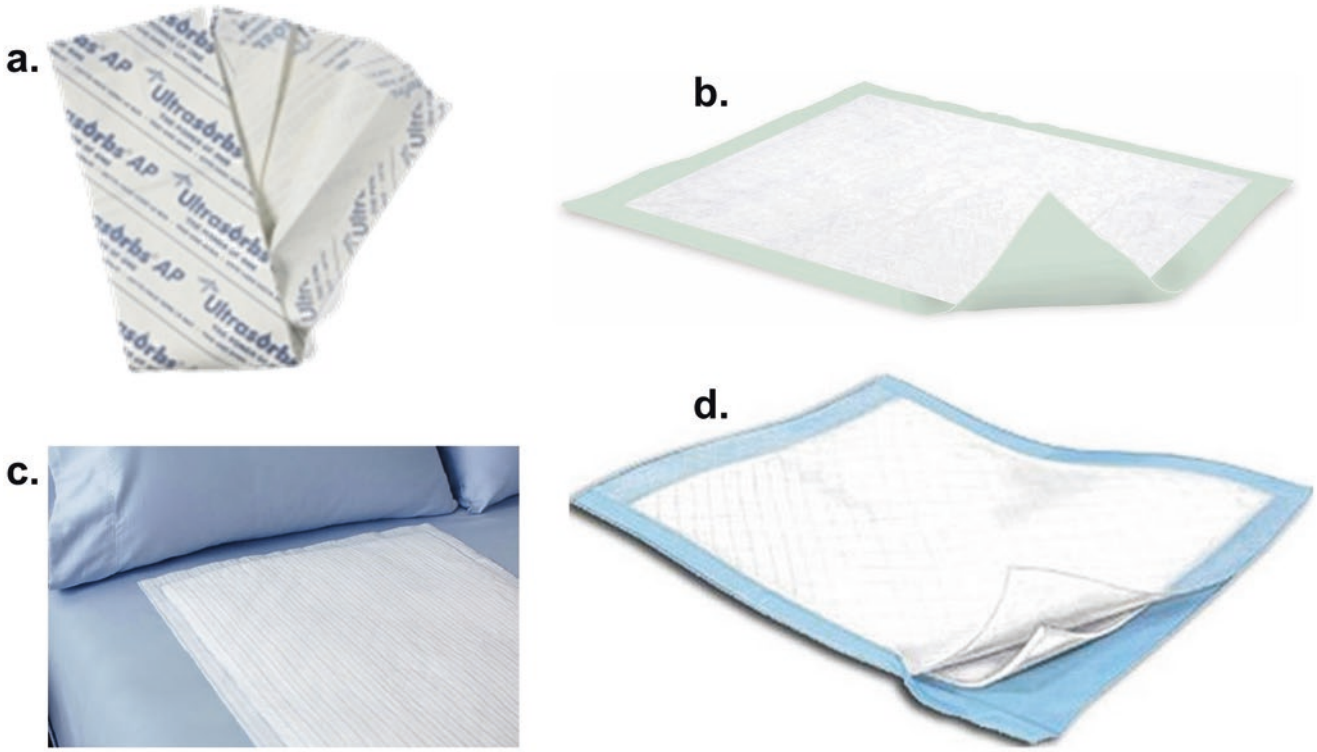

Fig. 6.21 Absorbent non-woven disposable underpads. (**a**) Ultrasorb—Courtesy of Medline. (**b**) Supersorb breathable underpads (Attends®)—Courtesy of Domtar Personal Care. (**c**) Underpad—Courtesy of Kimberly-Clark. (**d**) Fluff underpads—Courtesy of Covidien-Kendal

faster than vinyl products, helping to minimize associated utility costs.

- *Disposable underpads* are very common and utilized for a variety of care needs. These versatile products are commonly used not just for humans, but also for pet care protection and as a viable alternative to pets that need to void indoors. When choosing a disposable underpad product, the following should be considered: the size needed, the total absorptive capacity provided by the product, the ability to wick fluids away from skin, and the construction of materials, including the backsheet.

  Basic style of disposable underpads contain fluff only and are effective for light absorbency needs. The next level of underpads contain SAP granules that lock in fluids and help control odor. This style is indicated for moderate to heavier absorbency needs (see Fig. 6.21). Underpads containing both fluff and SAP provide a good combination that is softer overall and are comfortable against the skin. It is also very important to consider the backsheet material. Plastic backings are not very strong and should only be utilized temporarily or for shorter durations. Breathable backsheets assist in protecting the skin and avoid heat buildup as previously discussed. In recent years, disposable underpads have been constructed with durable, high-quality, and often breathable backsheets that allow for caregivers to lift and reposition individuals weighing up to 400 pound (lbs). These premium underpads are in high demand, and their use has grown exponentially in clinical care settings over the past decade. The premium features of these products include soft, cloth-like top sheets, rapid wicking and dryness layers to protect skin. Their popularity in the acute care setting owes to the perception that leaving the patient "open to air" with no bodyworn products is ideal in preventing skin breakdown and healing wounds, which is a paramount financial concern for long term care and acute care facilities that are subject to penalties and reduced funding for skin issues and patient complications while in their care.

Potential Complications

With proper application, potential complications related to the use of absorbent products can be minimized. However, the potential for complications still exists, and should be considered regardless of the care setting. Complications include:

- *Leakage* can occur if the wrong absorbency level or size is chosen or the product is not applied body-close.

- *Incontinence-Associated Dermatitis* (IAD) can occur with extended exposure to urine or stool. IAD can manifest as a painful, itchy rash leading to further skin breakdown. Chap. 8 reviews IAD. In long-term care facilities, the presence of IAD has been reported as 5.7% – rising to 20–27% in acute care – and is most often seen in patients using absorbent products for incontinence [18].
- *Skin irritation, breakdown and tissue injury* can develop with prolonged exposure to urine and feces. Pressure injury can develop if the absorbent product interferes with pressure relief; indeed, thickness, creasing or folding of the material can place added pressure on the skin. A soiled incontinence product can become stiff and hard against the skin and lead to increased pressure, if not changed appropriately [19].
- *Bacterial and fungal skin infections*, are often seen in patients in hot, humid climates or those in high temperatures. Bacteria and fungus will proliferate in these environments.
- *Bladder or urinary tract infections (UTIs)*, which are more prevalent in women and in patients with a combination of UI and FI. Immunocompromised people should not use underpads made from recycled paper, because of the risk of infection.

These potential complications can be experienced from the misuse of all absorbent incontinence products, or the use of poorly constructed or poor-performing absorbent products. Skin-related complications from incontinence are covered in Chap. 8. All potential complications should be considered and a mindset of prevention adopted to avoid adverse events.

Adverse Events

Adverse events seen with incontinence absorbent products are related to their misuse and failure to follow recommended best practices. Minor issues can become serious complications when products are not properly utilized, and these can have a huge impact on the wearer's quality of life. Possible complications include IAD, skin irritation and breakdown, wounds, bacterial and fungal infections, and UTIs, as noted above.

Embarrassment, severe psychological effects, social isolation, and anxiety can be experienced when individuals do not understand proper product selection and effective utilization. High levels of reported anxiety are associated with the perceived risk of poor absorbent product performance, a lack of discreteness and the need for complex care routines for product management [11].

Selecting the Appropriate Product and Best Practices for Use

Choosing the right product and absorbency level should be individualized to the wearers' needs, comfort level with the product type and level of incontinence. Combinations of absorbent incontinence products for different situations (e.g., disposable inserts for going to work, washable pants when staying at home) are likely to provide optimum management in terms of patient needs and cost-effectiveness. Best practices indicate that individuals should avoid the use of plastic and reusable cloth products, since these products trap heat and moisture, increasing the risk of skin breakdown. Ideally, consumers should choose a high-quality disposable absorbent product that provides a secure, body-close fit in a style that best fits their lifestyle and protection needs. When choosing a product, consider these key factors:

- *Gender considerations*: With the current technology and consumer innovations, many products are available that are specifically designed to meet the anatomical and lifestyle needs of men and women. Cottenden et al. [10] recommend that gender be considered when suggesting and/or purchasing products, because men and women are likely to prefer different designs. Both genders prefer discretely shaped pads. Pads for women are designed with varying absorbencies to support an active lifestyle. Working women will select a product based on social situations and anticipated activities [20]. Male guards provide features contoured to fit the male anatomy while being worn comfortably in close-fitting underwear, such as briefs or boxer briefs. The leading manufacturers now offer extremely absorbent and anatomically designed protective underwear styles featuring fashionable, garment-like patterns and thin designs that are very discreet under even tightfitting clothing styles (see Fig. 6.22).
- *Size and fit*: Choosing the right product and absorbency level can be nullified if the right size is not chosen. All absorbent products do not necessarily come in all sizes. Many individuals utilizing protective underwear and all-in-one briefs mistakenly believe that "bigger is better" when it comes to a product's ability to provide protection and choose a product one or two sizes larger than what they need. Not only does this allow the product to gap and leak, but it also provides unneeded excess material against the skin, which, combined with pressure, can cause discomfort and lead to skin breakdown and damaging pressure areas. Follow the manufacturer's guidelines when choosing an appropriate size, and remember that the product should fit securely and snugly against the body without being tight or uncomfortable.

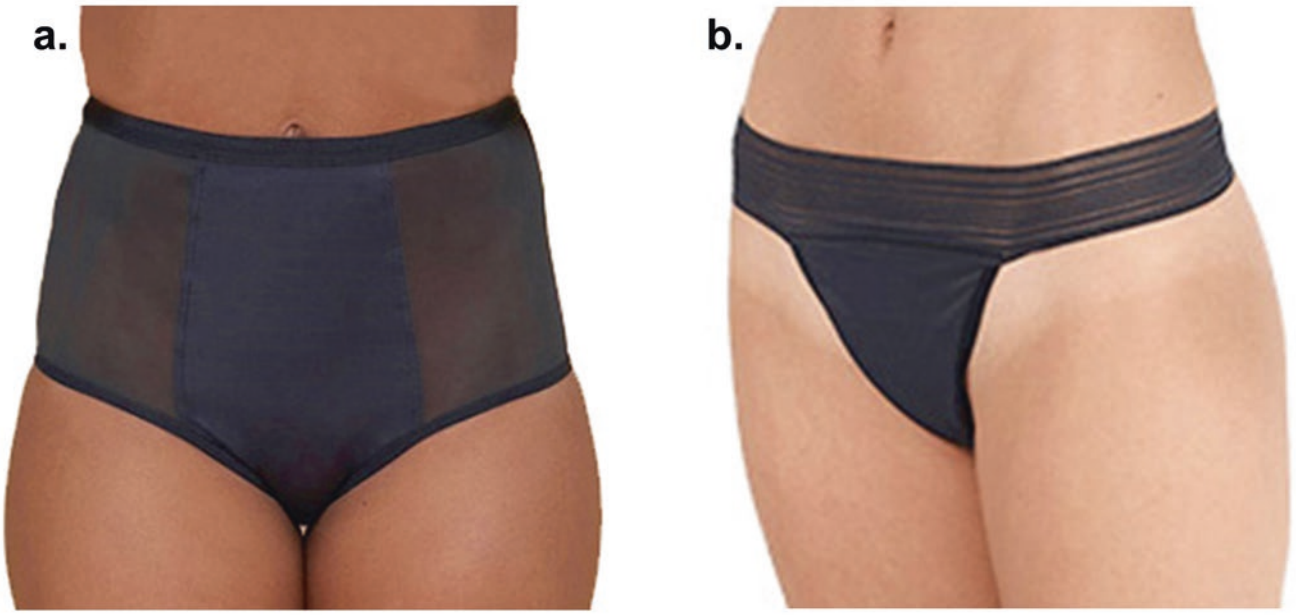

Fig. 6.22 Reusable products for women that claim to be anti-microbial, moisture-wicking, absorbent, and leak-resistant. (**a**) Brief; (**b**) Thong—Courtesy of Icon

Any visible gaps or loose-ness should be avoided. Bariatric sizes exist to support the needs of those individuals, and many manufacturers also have larger pad styles to meet the needs of larger or taller individuals. Carefully consider the indications for use and include all needs and instructions when choosing products.

- *Ease of use and ability to apply*: Considering the various product styles available, wearers can now more easily choose a product that is easy to apply and remove without compromising dignity and independence. Pantiliners, pads, male guards and undergarments are extremely simple to apply and change, and offer varied absorbency levels from very light to heavy UI. Products that utilize buttons may be more difficult for those with arthritis or dexterity issues. Those with belts sometimes feature "hook and loop" Velcro™-like fasteners that are easy to use regardless of dexterity. Nighttime pads are designed with wider backs to provide the same ease of use as a pad and additional needed protection at night, while lying down and reclining in bed. Protective underwear styles are easy to apply and help to normalize the condition because they most resemble normal cloth underwear. For heavier leakage needs that require changing the product multiple times, refastenable versions are available to allow for easy removal and application of a new product without having to remove one's pants. Briefs also offer refastenable tabs that allow for easy application and repositioning for a comfortable fit. Some are tape tabs with a refastenable zone that allow for multiple repositioning of tabs. Others feature the Velcro™-like "hook and loop" fasteners, which are commonly used in the higher quality brief designs.
- *Absorbency and odor control needs*: Select a more absorbent product for those individuals who experience heavy urine and/or bowel incontinence. All-in-one briefs provide the most odor control for individuals. While protective underwear are the most popular product style, due to their ability to normalize the condition, many are not able to meet the needs of heavy bladder and bowel incontinence. An all-in-one brief should be considered in such cases. All-in-one briefs are also indicated for those not capable of maintaining continence independently, for severe UI and for those with limited mobility. All-in-one briefs are often the best choice for individuals with double incontinence (both FI and UI) and those that are non-ambulatory. For those individuals often seen in extended care settings and in frail individuals receiving home care, the proper use of the right absorbent product is a vital part of a skin care and wound prevention program. The absorbent product can prevent or minimize skin exposure to urine and feces, while effectively containing odor and promoting dignity. The judicious use of products to contain urine loss and maintain skin integrity is a first-line defense for individuals at risk for skin breakdown, especially for continence care during the night.

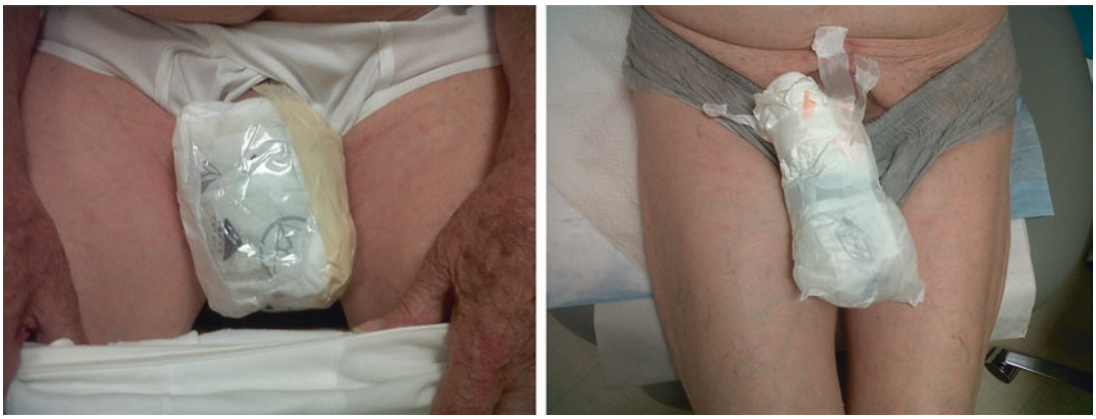

Fig. 6.23 Self-made containment products for urine loss

- *Fecal/Bowel incontinence*: Reusable products are not recommended for persons with FI because of stool staining. Additionally, pantiliners, pads, and male guards are not indicated for FI. High-quality protective underwear and briefs are best for effectively containing FI. An individual should always check the manufacturer's indications for use and ensure that the product chosen can effectively support their level of FI. It is important to remember that a product, regardless of style, should always be changed after an episode of FI.
- *Skin sensitivity*: Individuals with already fragile or compromised skin should choose products with the highest quality and absorbency. This will avoid risk of further breakdown and ensure that the product's absorptive function and capacity act to lock moisture away from the skin and keep the skin dry. Note that an undersized product can cause skin creases, temporary marks and pink/purple discoloration [21].
- *Cost concerns*: Many individuals purchasing absorbent products for incontinence are savvy shoppers and/or on a fixed budget. For those seeking maximum performance and cost-savings, high-quality disposable absorbent products with higher total capacities can be a good choice, as they can absorb multiple voids and incontinence episodes with no loss of performance or danger to skin integrity, while effectively containing leakage and odors. Most states distribute absorbent products for incontinent individuals receiving assistance from Waiver programs with a prescription from a health care provider. The National Foundation for Continence attempted to set performance standards for disposable absorbent products for adults for use by state Waiver Programs [12]. Most state programs purchase lower cost products, which may not be the best product for individuals with either UI and/or FI. Products purchased solely because they are "cheaper" may, in fact, require more frequent changing due to a lower level of features and absorbent capacity, and the wearer may also risk leakage, odor, and embarrassment. For these reasons, the total cost of the product should be balanced with realistic functional needs to ensure the product performs effectively, the wearer feels confident, and complications, both social and functional, are avoided.

For some individuals, reusable products may be a more economical alternative as their lifespan may be in excess of 200–300 washes. But there are associated laundry costs (e.g., detergents, energy, increased use of washing and drying machines) that may reduce this perceived cost benefit, and skin health and odor may be of higher concern with these product styles.

Cost can be the main barrier to purchasing any absorbent product for many men and women who experience incontinence. In these cases, homemade products, paper products (tissue, paper towels, toilet paper), and multiple layers of clothing may be substituted. Clinicians should identify any inappropriate use of homemade products to prevent adverse events from occurring. Figure 6.23 shows pictures of male patients who utilized several different homemade products to contain urine leakage.

Best Practices for Use

The practice of leaving an individual "open to air" at night, whereby the individual lies on a flat absorbent or reusable product, while asleep, has never been shown to be beneficial in preventing skin breakdown and should be avoided [22]. "Open to air" is an older nighttime incontinence care practice that is still followed in many long-term care facilities and more recently in acute care settings. The method entails

positioning an individual naked below the waist during nighttime sleeping hours on a disposable or reusable underpad without an absorbent product. Some nurses believe that the uncovered skin will be allowed to "breathe," providing a better climate for the skin. Most health care experts agree that the practice is not beneficial for the individual with either UI or FI and should be avoided.

- Avoid applying absorbent products too tightly, as an occlusive environment traps heat, and elevates skin temperature and moisture, which then produces friction and promotes microbial overgrowth. Products should fit against the body comfortably and securely.
- Products should always be changed immediately after an episode of FI.
- Perineal care and skin assessment should always be performed when changing an absorbent product to protect skin health and wellness and control odor.
- Those with nighttime incontinence should utilize a heavier absorbency product at night to effectively absorb heavier nighttime voids while protecting skin integrity. Many products are designed for "nighttime or extended wear." While these were previously only available as all-in-one briefs, both pads and protective underwear products are now available with targeted absorption zones to effectively support heavier nighttime voids.
- Heavier products for nighttime or extended wear are also useful for longer trips, flights or other situations where it may not be feasible to perform product changes.
- The practice of "double-padding" is not recommended, although many individuals will apply pad products inside of protective underwear to extend the life of the underwear product and reduce their need for constant protective underwear changing. Individuals should instead remove a used pad product and insert a fresh product into the underwear. While double-padding is often a cost-savings measure, the available choices and absorbency levels for pads make the practice unnecessary. If the wearer feels more confident with this practice, however, and they are mobile/ambulatory, the potential for complications are fewer and double-padding can be done. In these cases, ideally a "booster and/or insert pad," which does not have a moisture-proof lining, would be utilized, allowing for added absorbency while blocking urine transmission into the protective underwear product below. Booster pads can be changed throughout the day to extend the life of the protective underwear when needed (e.g., where one cannot change the product or remove clothing to change the product). For those who are bed-bound or individuals that are non-ambulatory, double-padding should not be utilized, since it provides another layer of padding and pressure against the skin that could lead to complications or skin breakdown.

Changing Products

With the current polymer technology found in quality disposable products for incontinence, wearers can confidently use one product throughout the day. For those with busy lifestyles that do not allow for constant changing, higher absorbency products are an effective choice. Protective underwear and all-in-one products may feature wetness indicators that provide a visual cue indicating how much of the product's absorbent capacity has been utilized, with directions on the right time to change the product. It is not uncommon to see change rates between 3.5 and 4.5 times per day in a clinical care setting without experiencing a decrease in quality of life or adverse skin effects. Absorbent products are not thought to cause UTIs, especially if they contain SAPs, and are changed after an episode of FI. Users at home often change products more frequently, depending on their personal hygiene preferences and comfort when wearing the product.

Preventing Skin Breakdown

Individuals with incontinence, whose urine leakage is being contained through use of an absorbent product, are at increased risk for skin breakdown. Moisture from urine, stool, and repeated cleansing can cause increases in the friction coefficient of the skin resulting in mechanical injuries, such as skin chaffing from contact with linens, absorbent products, or water soluble irritants, like detergents. Excessive moisture against the skin can also lead to maceration (MASD) and epidermal injury (see Chap. 8). Regardless of where products are being utilized (at home or in a clinical care setting), it is best to keep risk factors in mind and adopt a mindset of prevention to avoid any complications or adverse events that could stem from the use of incontinence products.

For those with sensitive skin or limited mobility, preventive skin care products designed to support individuals with incontinence can be utilized to moisturize and protect skin from irritation and breakdown (see Chap. 8). These products are developed specifically to work with absorbent products for incontinence and contain ingredients and features (such as being pH balanced) to help prevent issues related to absorbent product use. Many products on the market are "no-rinse" and cover several functions (i.e., cleansing, moisturizing and protecting) to help make skin care faster and easier while reducing the potential for complications. Skin barrier products, such as those containing zinc oxide, repel irritants and moisture by providing a water-repelling coating to the skin. These can be used to prevent skin breakdown or as therapy for skin damage due to incontinence.

Evidence-Based Research

Few absorbent products for incontinence have been subjected to user and clinician evaluation. Very little evidence on product effectiveness or comparisons between similar products have been conducted and published in the medical literature [6]. Research and development by product manufacturers remains an ongoing factor for absorbent products for incontinence due to their projected growth rate in the market. The majority of research on product performance has centered on non-woven disposable products with very little conducted on woven reusable products. Research conducted on reusable products has indicated that they do perform well overtime [23]. A Cochrane review by Fader et al. [13] for moderate to heavy UI or FI in men and women found only two eligible clinical trials carried out in the previous 10 years and both were of bodyworn absorbent products. Manufacturers seeking to capture more market share by providing valued innovations are continuing to invest and explore potential new features and benefits that will connect to the mindset of consumers and buyers. For all in pursuit of quality outcomes, efforts to improve products center on normalizing the condition and accommodating more active lifestyles. Clinicians and researchers will continue to evaluate the effectiveness of products, as well as their potential for complications and adverse events, in pursuit of improving care outcomes in the various healthcare settings.

Getliffe et al. [11] conducted semi-structured interviews with women ($n = 99$) with light UI to determine the impact of pad use on women's quality of life and to rank pad characteristics by their importance. Light incontinence was defined as having UI that occurs at least once a day and is contained using an absorbent pad with an absorption capacity designed for light incontinence. The pads were supplied by the National Health Service in the United Kingdom. The majority of women interviewed were age 50 and older ($n = 79$). The dominant factor impacting women's lives was achieving effective and discrete containment of urine leakage as seen in Chart 6.3 which lists the super-ordinate themes. Women interviewed in this study were extremely anxious about "hiding the problem" from others and about "ease of use," particularly in changing and disposing of used pads. Women reported their preferred pad characteristics for day or nighttime use. A top concern was the ability of the day and night pad to hold urine without leaking. The ability to stay in place was particularly important at night (77.8%), but less so during the day (54.5%). Notably, the ability to contain smell was ranked second only to holding urine for daytime use (75.8%) and was also identified as important at night by over half the sample (54.3%) of women interviewed. Chart 6.4 summarizes the product characteristics that ranked in the top five for day or nighttime use.

Chart 6.3 Themes identified from interview data indicating key domains for development of QOL measures for women with light UI using absorbent products [11]

Super-Ordinate Theme: Containing the Problem	
Holding Urine: Absorbency, Fit and Ability To Stay Place	
Hiding the Problem: Discreteness, Odor Control	
Ease of Use: Changing Pads, Disposal, Costs and Extra Work	
General Comfort: Size, Position, Material	**Perception of Self:** Normality, Femininity
Skin Health: Soreness from Dry Pad/Wet Pad	**Inter-Personal Relationships:** Partners/Sexuality, Family/Friends, Working Life
Sleep: Comfort, Disturbance	**Coping with Incontinence:** Personal Coping Strategies in Familiar and Unfamiliar Situations

Themes identified from interview data – indicating key domains for development of QOL measures for people using absorbent products.

Chart 6.4 Summary of most common product characteristics ranked as high priority to women with day time and night time UI [11]

Top Five Characteristics (day)	% of Women (n=99)	Top Five Characteristics (night)	% of Women (n=81)
To hold urine	83.8	To hold urine	93.8
To contain smell	75.8	To stay in place	77.8
To stay in place	54.5	To contain smell	54.3
Discreteness	41.4	Comfortable when wet	54.3
Comfort when wet	40.4	To keep skin dry	48.1

Different types of product research encompass designs and performance using laboratory testing. This method often is employed to understand and manipulate the materials that comprise the products and their performance under different conditions. In the clinical care setting, much research is conducted to evaluate absorbency performance in use and to measure skin health and outcomes related to absorbent products and their care delivery. Additional modeling techniques include clinical trials of products and evaluations of service delivery models, [24] as well as the influence of other factors on products, including application, sizing, changing practices, and related associated factors. It is clear that many factors that contribute to the success or failure of absorbent products, and more evidence-based research is needed to better understand the varying support needs of age and gender, combined with caregiver factors both at home and in clinical settings. Recommended research priorities also include more focus on the needs of users with FI [24]. It is clear that research will improve and be more valuable if the user/consumer/patient experience, as well as the desired outcomes, can be effectively captured.

Brazzelli et al. [9] conducted a systematic review of randomized and quasi-randomized controlled trials examining the effectiveness and consequences of absorbent products used to contain UI or FI. This review did not state an age preference for the participants of included studies, which puts into question its inclusion in this review. The studies evaluated required only that participants be adults with UI or FI. However, in the two studies reporting skin condition outcomes, participants were identified as residents on hospital nursing wards, suggesting long-term care. From one study, the authors determined that patients wearing disposable bodyworns were 92% less likely to develop skin problems than if they wore non-disposable bodyworns. However, disposable underpads did not provide any protective effect over non-disposable underpads. In fact, the trend was towards the effectiveness of the non-disposable underpads, but this result was not significant. In the second study reviewed, residents using disposable bodyworns were 60% less likely to develop skin symptoms (tingling, itching, burning, pain) and show changes in skin color compared with those using disposable underpads. However, neither product was more effective at maintaining skin integrity. Superabsorbent underpads were more effective at preventing skin alterations and changes in skin color than fluff pulp underpads, while superabsorbent bodyworns only reduced the risk of skin alterations compared with fluff pulp bodyworns. It is important to note that the data from this study reporting the outcomes of skin alterations, color and integrity were derived from graphs presented in the original paper. These results suggest that disposable bodyworns are more protective against changes in skin condition than non-disposable bodyworns or any kind of underpad tested in these studies. Many of the products identified in these two studies are no longer available or are not available in the US.

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Urologic Devices

7

Donna Y. Deng

Introduction

Though textbooks and lectures focus on surgical and pharmacologic interventions for urinary incontinence (UI), a comprehensive description of urologic devices that are part of the anti-incontinence treatment armamentarium, or that provide containment of urine leakage is lacking. Occlusive devices for preventing UI are available for men and women. In women, a device can be used at the external urethra, in the urethra (intraurethral) or via the vaginal (intravaginal) [1]. Many individuals with incontinence do not wish or need invasive treatments, and these devices may be satisfactory therapeutic answers for them. For others, these devices can be diagnostic tools to decide whether or not more invasive treatment is the answer.

Urostomy Pouch

Definition

A urostomy is a type of urinary diversion utilized when the bladder can no longer be used to store or expel urine or must be removed in cases of cancer. It is created by using a piece of the intestine (conduit) for urine to flow through (see Fig. 7.1). The ureters are sewn to this piece of intestine on one end and the other end is brought outside of the body and sewn to the abdomen to form a stoma. The urine travels through the ureters to the piece of the intestine and out of the stoma that is created at skin level. The urine is not controlled, so a pouch (bag) is attached to collect the urine (see Fig. 7.2). This is an example of a surgically created incontinence mechanism.

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Indications

If the bladder can no longer be used as a vessel to store or evacuate urine, some type of urinary diversion must be created. Most often, this occurs in cases of muscle invasive bladder cancer where a radical cystectomy is performed. Other examples include bladders with poor compliance and/or capacity due to radiation damage, neurologic disease (e.g., spina bifida) or spinal cord injuries. There are other cases where the bladder may be in functional condition, but the urethra is beyond repair and cannot provide any continence mechanism. In such cases, the bladder is bypassed in favor of a urostomy. Urine is contained by use of a urostomy pouch.

Materials

A urostomy pouch, the device that contains the urine as it exits the stoma, is made of clear or opaque plastic, held to the skin with an adhesive barrier (flange) and includes a spout at the bottom to drain the urine. The pouch and accompanying supplies are called "appliances." There are a variety of pouches available as seen in Fig. 7.3. They are odor-proof, lightweight, gentle on the skin, and low profile. There are many different options to fit diverse needs and choices. No one choice works for all. Health care providers, often specialist ostomy nurses or urology nurses, should have various samples to assist the patient in finding the one that works best [2].

Designs

There are two basic barrier designs or shapes: flat or convex. Flat barriers (see Fig. 7.4) are used for standard stomas with good protrusion. Convex or curved barriers (see Fig. 7.5) apply gentle pressure on the skin around the stoma, helping the stoma protrude further. These barriers work very well for stomas that are flat or below skin level or protrude less than

D.K. Newman et al., *Clinical Application of Urologic Catheters, Devices and Products*, DOI 10.1007/978-3-319-14821-2_7

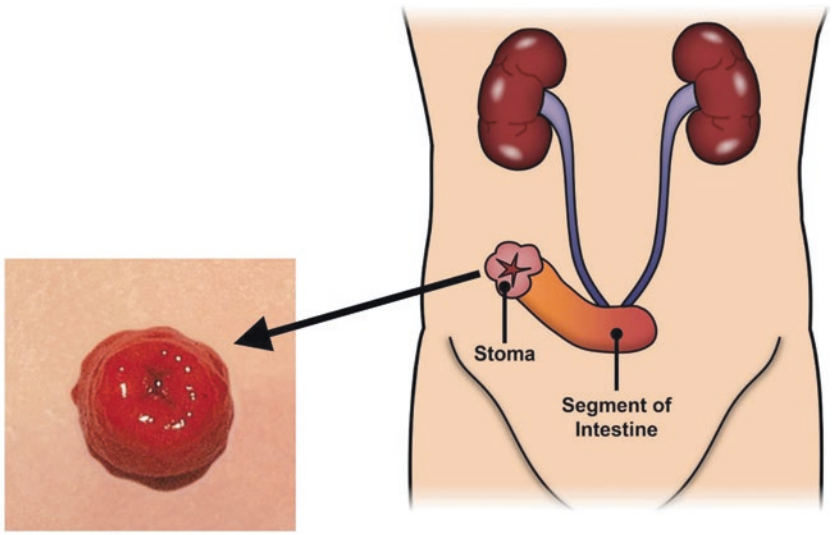


Fig. 7.1 Anatomical view of Urinary Diversion with Stoma—Courtesy of Diane Newman

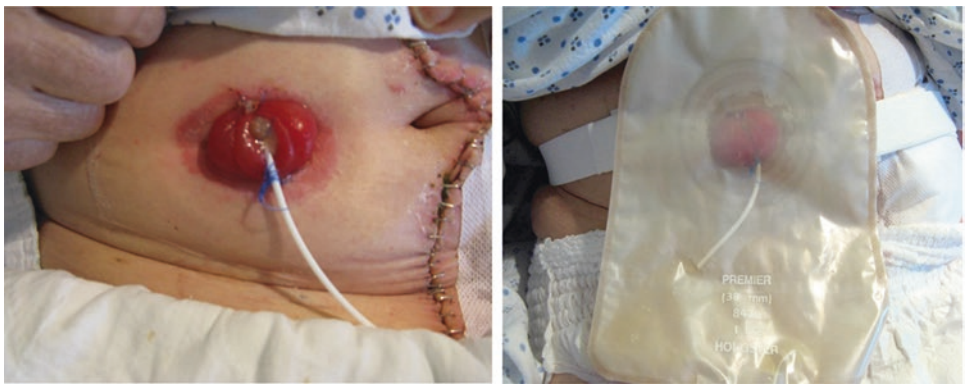


Fig. 7.2 Newly created Urostomies without and with bag and belt—Courtesy of Ave Preston

Fig. 7.3 Various available Urostomy Pouches. (**a**) Little Ones® One-piece Urostomy Pouch—Courtesy of Convatec. (**b**) One-piece system with MicroSkin adhesive barrier plus anti-reflux valve and integral Thin MicroDerm washer transparent—Courtesy of Cymed. (**c**) One-piece Convex Urostomy—Courtesy of Hollister, Inc. (**d**) ActiveLife® One-Piece Convex Urostomy Pouch—Courtesy of Convatec. (**e**) SenSura® Mio—Courtesy of Coloplast Corp.

Fig. 7.4 Flat barrier—Courtesy of Coloplast Corp.

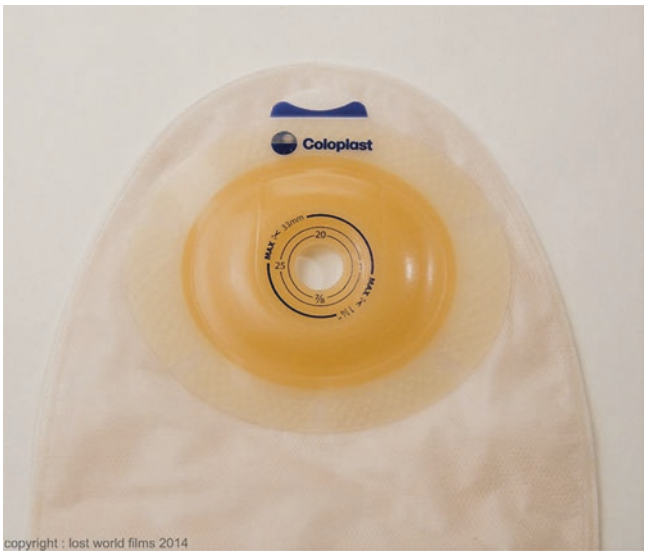


Fig. 7.5 Convex or curved barrier—Courtesy of Coloplast Corp.

one inch, or where the abdomen is very soft or the skin is not flat around the stoma.

A regular/standard wear barrier, or the more commonly used extended wear barrier, is also available. Selecting the most appropriate barrier depends on the desired or required frequency of appliance changes, characteristics of the drainage (fecal versus urine; liquid versus formed), volume and cost. Ideal barriers should protect the peristomal skin from urine, provide a safe and secure seal, be gentle to the skin during flange removal, and provide cost-effective stoma management.

In general, regular wear barriers are less resistant to liquid stool and urine. Shorter wear times are expected with a regular wear barrier (usually no more than 1–2 days). These types of barriers tend to "melt" more readily with exposure to liquid, permitting unwanted peristomal skin exposure and the potential for skin irritation if left on for too long. Regular wear barriers work well for formed stool, which is typically found with colostomies. Because stool has less liquid content and the stoma tends to function less often, a regular wear barrier will not "melt" as easily and longer wear-times can be achieved.

Extended wear barriers, on the other hand, are formulated to provide greater resistance to liquid stool and urine (see Fig. 7.6a, b). Consequently, longer wear-times with these products are more realistic. Some of the extended wear barriers also contain substances that absorb the moisture from the stool or urine, causing the barrier to swell or "puff-up" around the stoma. This swelling allows for a better seal and resists undermining of the stool or urine under the flange. The barrier will move with the stoma and normal peristalsis, and will not occlude or block the opening of the stoma. There also tends to be greater tack and adhesion with extended wear products. While this adhesion assists with longer wear times, care must be taken with flange removal to avoid peristomal skin damage. Extended wear barriers are an appropriate choice for people who have urostomies or ileostomies, or

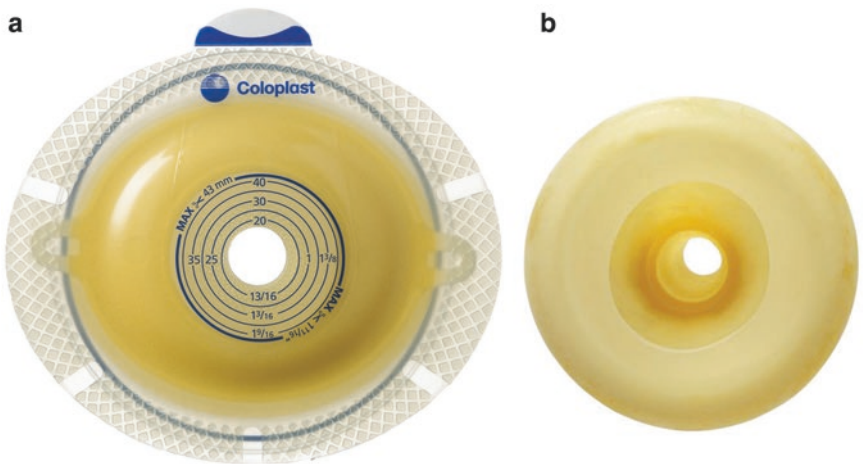


Fig. 7.6 Extended wear barriers. (**a**) 2-piece pouching wear barrier (SenSura Flex)—Courtesy of Coloplast Corp. (**b**) Extended wear barrier with inner flap—Courtesy of Hollister, Inc.

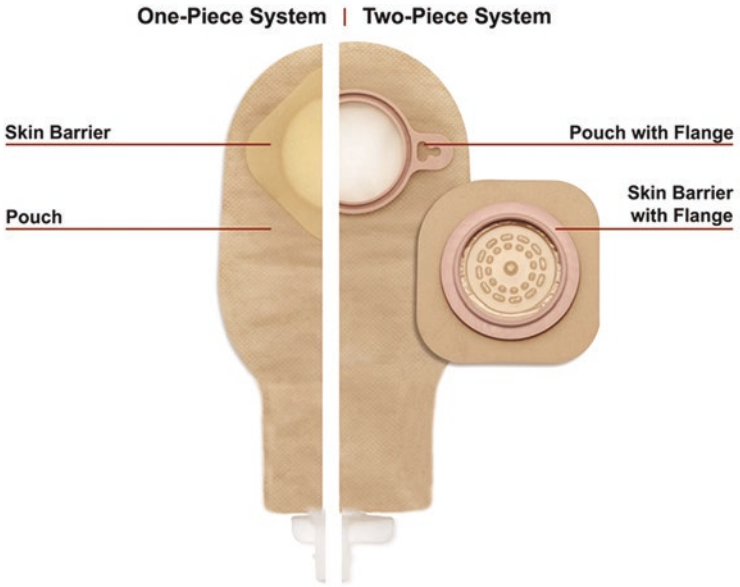


Fig. 7.7 One- or two-piece Urostomy Pouch Systems—Courtesy of Hollister, Inc.

those who have liquid stool with colostomies. In general, extended wear barriers tend to be more expensive. However, costs may be offset by the fact that the frequency of flange changes will likely be less with extended wear barriers. Additionally, if the peristomal skin is well protected, use of additional accessory products, such as powders, can be eliminated. Some product styles, such as convex flanges, may only be available as extended wear barriers.

Urostomies include one- or two-piece systems (see Fig. 7.7). In a one-piece system, the barrier and pouch consititute one unit. The advantages of one-piece system include their application in fewer steps and flat positioning against the skin. Patients with arthritis, who may have minimal hand strength and dexterity and limited eyesight, may find one-piece pouches easier to apply. A one-piece system adheres easier where the skin is uneven around the stoma and the pouch is less visible under clothing. A two-piece system has a separate barrier and pouch that connect together. It is less flexible than a one-piece pouch. The two-piece system allows the wearer to change the pouch for activities, such as swimming or intimacy.

Techniques/Procedure for Use

Emptying the Pouch

In general, the pouch should be emptied when it is about 1/3–1/2 full to decrease the risk of leakage. This is typically every 2–3 hours (h) for most patients. The patient can sit or stand over the toilet. If sitting, the patient can place the spout of the pouch between their legs, open the spout and point it down into the toilet, and let urine drain out of the pouch. The patient should wipe the spout with toilet paper to dry and then close it.

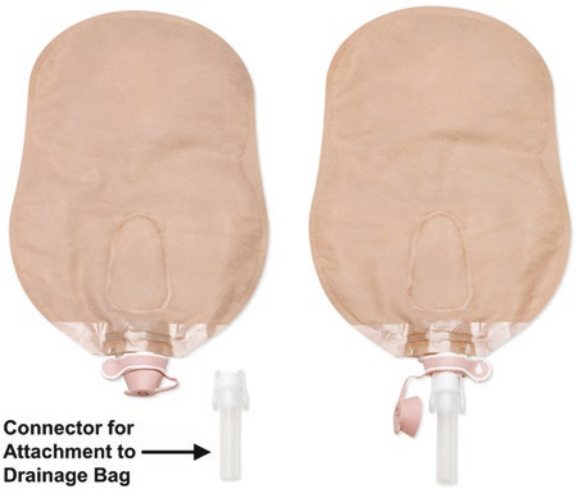


Fig. 7.8 Urostomy pouch with a special connector—Courtesy of Hollister Inc.

Pouch Drainage

A larger capacity drainage bag is available for nighttime drainage (see Chap. 5). It is attached to the spout of the urostomy pouch with a special connector that is included with the pouch (see Fig. 7.8). This larger urine bag stays connected to the pouch during sleep so there is no need to wake up and empty the pouch. The drainage system must be emptied and rinsed out with warm water every day [3]. Some health plans provide new bags each week. If bags are reused, the method for cleaning varies. Some advocate not using vinegar. The following are some tips for preventing or dealing with accidents during sleep:

- Use an absorbent pad under the sheet to protect the mattress in case of a leak at night.

- Put the tubing inside a pajama leg and use a securement device or tape the tubing to the leg to keep the tubing from kinking and causing urine leakage.

Leg bags are medium-sized urinary bags that attach to the pouch at one end and can be secured to the leg (see Chap. 5). Leg bags have a larger capacity than a pouch, but less capacity than a night bag. They allow for storage of a larger amount of urine before emptying is necessary, which can be useful during travel or long meetings. The bag has two straps that hold it in place against the thigh or lower leg, depending on personal preference or type of clothing worn. The care is similar to the nighttime bag.

Table 7.1 outlines how to change the pouch system. Skin around the stoma and under a pouch/barrier should always

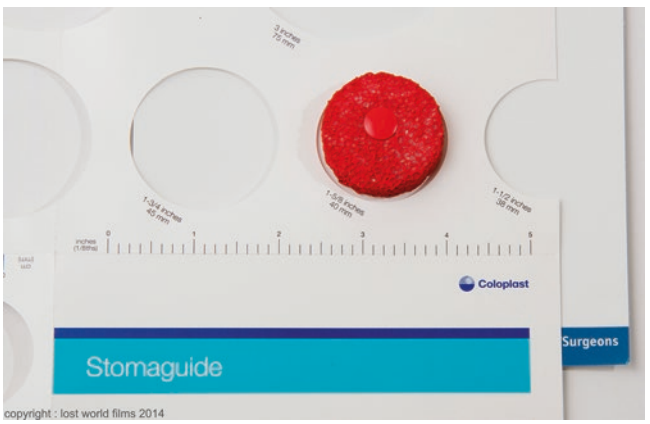
Table 7.1 Changing the urostomy pouch system

Patients should change the pouch system 2 or more times per week or if it leaks. The best time to change the system is in the morning, before drinking, when there is less urine flow. Steps to change the pouch system are as follows:

1. Gather supplies—washcloths, hair dryer (if used), measuring guide, curved scissors, marking pen, plastic bag for garbage, new pouch/barrier, and other accessories (e.g. sealants, skin barrier paste or powder, adhesives, solvents, belts, tapes)

2. Remove pouch, using push/pull technique. Start at the top; use one hand to pull up barrier and the other to gently push skin away from barrier. Place in plastic bag/garbage can.
3. Absorb the urine while changing the pouch by placing a piece of rolled paper towel or tampon in the stoma. As changing the pouch becomes quicker, using a piece of paper towel or gauze on top of the stoma is usually adequate.

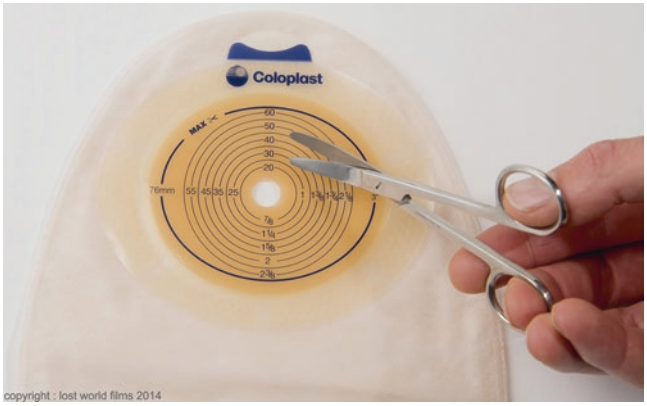
4. Prepare new pouch/barrier. Measure stoma with measuring guide (Stomaguide). The barrier should fit right around the stoma, not on it or leaving skin exposed.



(continued)

Table 7.1 (continued)

5. Trace the pattern on the back of the barrier or cut out the opening using the measurement on barrier. Do not remove the backing to expose the sticky surface yet. Patients won't need to measure the stoma each time once it is stable, usually after 6 weeks, at which point pre-cut pouch/barriers can be ordered and used. Patients can also pre-cut barriers so they are ready for use.



6. Wash skin around stoma with warm water only. Soap can leave a residue. Dry well with towel or hair dryer.
7. Inspect skin for redness, irritation, and wounds. Treat accordingly.
8. Be sure the spout at the bottom of pouch is closed before placement.
9. Remove backing on barrier to expose the sticky surface. Apply pouch/barrier. Be sure the skin is clean and dry. Center the opening of the barrier over the stoma and press down around the stoma and then the rest of the barrier. Avoid getting urine on barrier as it will not stick. Remove tampon or paper towel after applying barrier and before snapping on pouch or right before placing a one-piece pouch on. *It is very important to keep the skin around the stoma dry while placing the barrier. Moisture under the barrier prevents it from sealing well and can cause skin breakdown.*
10. Apply gentle pressure with hand for at least 90 seconds as the barrier is pressure and heat sensitive. The barrier can be warmed before placing on the skin with a hair dryer or held between the hands for a few minutes. This will assure a better seal and prevent leakage. Adjust hold time according to how well the pouch adheres.

be healthy and intact. The best way to keep skin healthy is by preventing leaks and keeping urine off the skin. Other ways to keep skin healthy include: (1) changing the pouch on a routine basis; (2) using only warm water to cleanse as soaps and lotions can leave a residue and the pouch/barrier will not adhere; (3) ensuring skin is clean and dry before applying pouch/barrier; (4) ensuring the barrier opening fits right around the stoma, not on leaving too much skin exposed; (5) carefully clipping or shaving hair where the barrier sits if it interferes with the pouch sticking, (6) always change a leaking pouch/barrier. Do not change the pouch/barrier too often, use harsh chemicals or roughly remove an old pouch/barrier.

Problems/Complications/Adverse Events

Complications and adverse reactions can occur and are outlined in Table 7.2. The patient should be instructed to assess the stoma daily to identify problems early and monitor the skin under the barrier with each pouch/barrier change. Pay close attention if the skin is irritated, red or weepy, or if there is a rash, broken skin or small wounds.

Leakage of urine around the urostomy is a significant problem that causes patients much distress. It can be caused by retraction of the stoma, uneven skin around the stoma, or poor barrier fit. This would also be considered a failure of the urostomy's purpose. Table 7.3 outlines tips and tricks to avoid and manage leakage of urine around the urostomy. Usually one of these tricks will solve the problem. Patients should be advised to be prepared and carry an extra pouch with them at all times.

A hernia is a bulge in the skin around the stoma (see Fig. 7.9) where the intestines have slipped through the muscle and fascia of the abdomen. This occurs because the stoma is brought through a surgically made opening and the fascia is inherently weaker in this area. Clinicians do not know how to prevent hernias around the stoma but some strategies to decrease their risk are outlined in Table 7.2.

Patient Information

Teaching Tools

There are many resources that patients can access for urostomy support. Several are listed in Table 7.4. There are several manufacturers of ostomy products (e.g., Coloplast, Convatec, Cymed, Hollister, Marlen, Nu-Hope) and supplies are usually sent to the patient's home by mail after the patient is discharged from the hospital [4]. Table 7.1 lists a range of supplies needed when changing an ostomy pouch. Most insurance companies require a prescription from the prescribing provider for ostomy supplies. The orders are usually set up before the patient is discharged from the hospital or as adjustments are made during the months following the urostomy surgery. To re-order supplies, the patient should contact the supply company monthly. Insurance will cover 50–100% of the cost, but

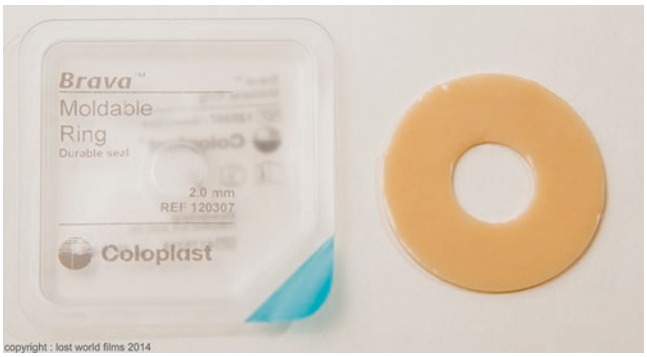
Table 7.2 Urostomy problems and complications

Problem	Reason	Solution
Skin irritation	• Allergy to barrier adhesive • Urine contact from improper pouch fit or leaking pouch	• Changing to a different company's product generally solves the issue. • Make sure stoma opening fits close around the stoma, leaving no skin exposed • Change leaky pouch as soon as possible as skin exposed to urine over time may develop urine crystals or warty and discolored growths. • Treat skin irritation by: (1) exposing the irritated skin to air for 20–30 min during pouch changes, and (2) applying a skin barrier on clean and dry skin around the stoma. Allow the skin barrier to dry and then apply a new pouch.
Open or broken skin	• Infection (see below) • Urine leakage or wetness under barrier (see Table 7.3) • Allergic reaction to barrier (see above)	• Crusting the skin ◦ Sprinkle stoma powder over broken skin ◦ Brush off extra powder ◦ Gently tap on skin barrier
Fungal infection of stoma or peristomal skin	• Secondary to antibiotic use	• Nystatin topical powder to treat the rash and above techniques to keep skin dry around stoma
Urinary tract infection (UTI)	• Immunosuppression • Stress	• Maintain hydration by drinking enough fluid to keep urine a clear, light color. (e.g., 48–64 ounce (oz) fluid in 24 hour period) • Drink cranberry juice or take cranberry pills, probiotics or other drugs (e.g. Hiprex with Vitamin C) to prevent UTI
Peristomal Hernia	• Weakness of fascia around the stoma	• Decrease pressure behind the stoma for the first 6 weeks after surgery by: ◦ Avoiding lifting >10 lbs. ◦ Avoiding excessive coughing and straining ◦ Avoiding strenuous exercise or activity • Use good body mechanics when lifting and avoid using abdominal muscles to lift • If a hernia interferes with fitting of the stoma pouch, a hernia support belt can be fitted.

Table 7.3 Tips and tricks to managing urine leakage around the urostomy

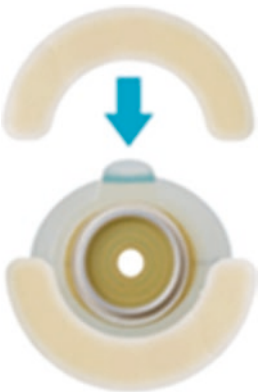
1. The pouch should be emptied when 1/3 to 1/2 full
2. The skin should be clean and dry before applying a new pouch or barrier
3. Pressure should be applied on the new pouch or barrier during application and the pouch and barrier should be changed on a regular basis.
4. Changing the Pouch: The amount of time a patient is able to wear a pouch before changing it may be shorter when in a hot climate, or when participating in sports or swimming. The barrier absorbs perspiration and water so the barrier will not stick properly and wear out earlier.
   a. If the pouch/barrier leaks once during the day, change the pouch/barrier.
   b. If the pouch/barrier leaks more than once during the day, change the pouch and consider use of the following:

- Ostomy belt snugs the barrier closer to the skin, strengthening the seal
- Moldable ring fills in uneven gaps or creases in the skin, absorbs moisture without breaking down the skin and acts like caulking.



- Skin barrier paste can be also used to fill or caulk uneven skin contours to create a flatter surface, thus preventing drainage from getting under the ostomy skin barrier.

- Skin barrier paste strips can be placed around the edges of the barrier to provide extra security and prevent the edges from rolling up.



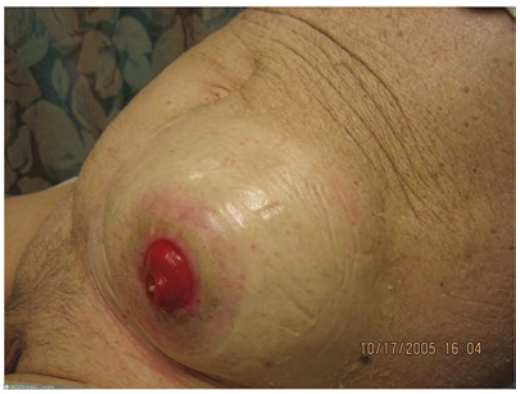


Fig. 7.9 Peristomal hernia

Fig. 7.10 Mini Urostomy pouch with cover—Courtesy of Coloplast Corp.

Table 7.4 Resources for ostomies

- The United Ostomy Association of America, Inc. is a volunteer-based health organization providing education, information, support, and advocacy for people with an ostomy. Their contact information: (800) 826–0826 or www.uoaa.org
- The American Bladder Cancer Society website, www.bladdercancersupport.org, is run by bladder cancer survivors
- The Bladder Cancer Action Network provides information about local support groups and online support. In addition, they offer a handbook "Bladder Cancer Basics for the Newly Diagnosed" free upon request at www.bcan.org
- The Ostomy Book: Living Comfortably with Colostomies, Ileostomies and Urostomies" by Barbara Door Mullen and Terry McGinn
- 100 Questions & Answers about Bladder Cancer" by Pamela Ellsworth, MD and Brett Carswell MD

each plan is different. Most plans will cover at least ten barriers and ten pouches per month, along with necessary accessories. Different patients often have different needs in terms of the type of pouch, adhesive, and belt, and the quantity of supplies needed, depends on how well the appliances fit on the stoma. Much of this is determined by adjustments made by the ostomy and/or urology nurse with the patient if there are problems using the standard pouch or barrier. Patients should leave extra time in ordering, and be mindful when leaving on long trips to make sure they have enough supplies on hand. Other areas that should be reviewed include:

- *Clothing*: After surgery, loose clothing will be most comfortable as the abdomen is swollen. After 4–6 weeks, patients can wear their normal clothing. They can tuck the pouch in their pants or over their pants covered by a long shirt. The pouch should not be visible under clothing.
- *Lifestyle Accessories*: Some companies offer additional lifestyle accessories to cover the pouch, make it discreet, hold it tight against the abdomen in a slimmer profile and offer more support for the pouch. A tube top or belly band may be placed over the stoma and pouch to achieve a slimmer profile. These items are not covered by insurance.
- *Changes in urine*: Remind patients that there will be mucus (white flecks) in their urine due to the mucus production from the intestinal conduit, which is a short piece of intestine. The amount of mucus usually decreases over the first year to where it is barely present. When there is an increase in mucus in the urine, it may signal a UTI. Foods that may cause urine odor include: fish, onions, garlic, and asparagus. Beets often cause urine color to turn red and can be alarming to an unsuspecting patient. Some medications can also cause an odor or change in the color of urine.
- *Bathing and Showering*: People with urostomies can shower or bathe with or without the pouch/barrier on. If bathing without the pouch on, water will not flow into the stoma. A soap without residue or oil should be used on the skin around the stoma and rinsed off well to prevent issues with the barrier adhering. No soaping of the stoma is necessary, as just rinsing with warm water is enough.
- *Intimacy*: The pouch should be emptied before sexual relations. A beige pouch, a pouch cover or intimate apparel can hold the pouch close to the body and keep it hidden from sight if so desired. A smaller pouch can be worn during this time if the patient so desires (see Fig. 7.10).
- *Exercise or Sports*: Patients with a urostomy will be able to return to their normal activities when they have fully recovered from the surgery and when approved by the physician. The patient would be prudent to avoid lifting with the abdomen or rough contact sports for the remainder of their lives. Heat and moisture may decrease the amount of wear time, causing the pouch/barrier to have to be changed more often. The pouch should be emptied

before activities. Tape or elastic barrier strips can be added around the edges of the barrier before swimming to prevent the pouch from lifting off. Special smaller pouches can be worn for exercise.

- *Travel*: It is very important for the patient to bring all ostomy supplies that will be needed for a trip. If flying, one to two sets of ostomy products should be in the carry-on case. Scissors are not allowed through airport security so use pre-cut pouches in the carry-on bag and pack the scissors in the checked luggage for use at the destination. Patients should carry a medical travel card that explains the ostomy and supplies in case of security issues.

Penile Compression Devices

Definition

A penile compression (occlusive) device is a containment device for men designed to fit around the shaft of the penis and externally compress the urethra to reduce UI (see Fig. 7.11) The patient releases the device when he wishes to completely empty the bladder. These devices take the form of a clamp and are often referred to as a "penile clamp." They are usually placed halfway down the shaft with the compression part of the device on the underside of the penis, compressing the urethra [5].

Indications

These devices can be used in men with mild to severe UI. Most commonly they are used for men with stress UI due to a weak urinary sphincter, which can occur after radical prostatectomy [6–9] or external beam radiation treatment for prostate cancer, or after transurethral resection of prostate "TURP" for benign enlargement of the prostate. In other cases, a weak urinary sphincter may be a result of congenital bladder anomaly or congenital spine malformation (spina bifida), or spinal cord injuries. Penile compression clamps should not be used in men who have an indwelling urinary catheter.

Fig. 7.11 Cunningham penile compression device in place

Materials

Penile clamps are typically composed of a plastic and/or metal frame with a foam or rubber internal cushion that compresses the urethra. While these clamps provide some advancement for controlling urinary dysfunction and protecting against bladder malfunction, improvements are needed [8]. A penile compression device does not completely eliminate urine leakage when applied at a comfortable position. A contoured designed clamp that "envelops" the penis without causing circumferential compression and adapts to allow for penis misalignment is needed [10]. There is need for a penile compression device that provides optimum comfort and that is easy to apply and remove, while sufficiently preventing urinary leakage. Another improvement would be a device that provides an absorbent mechanism conveniently, effectively and comfortably attached to the compression device.

Designs

There are many designs and manufacturers of penile compression devices. Table 7.5 provides a comprehensive list and description of currently available clamps. Many are made by small companies and samples may not be readily available in the office for patients to try before ordering. However, companies are usually happy to send samples, if requested.

Technique/Procedure for Use

Applying an occlusive penile device can be a problem for men with decreased manual dexterity, poor vision and/or a retracted penis. Have the man apply the clamp while observing and coaching him. Most penile compression devices operate on these similar principles:

- Light pressure on the urethral canal on the underside of the penis is the key to preventing urine leakage.
- The necessary pressure is achieved by device compression on the underside of the clamp
- For proper fit and comfort, shape the upper part of the clamp (in clamps using flexible parts).

Table 7.5 Penile compression devices: description and considerations for use

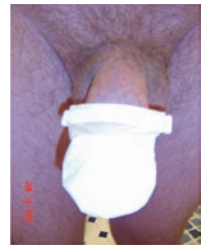
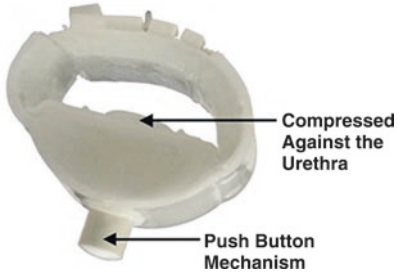
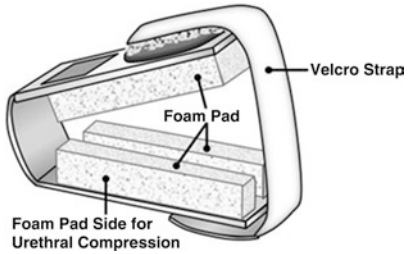
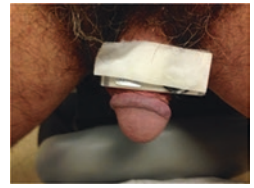
Name and Manufacturer	Device	Description	Use Considerations
ActiCuf Disposable Pouch GT Urological		• Combination penile clamp and absorbent collection pouch that is available in one size	• Penis is placed inside the pouch • Should be adjusted so it is comfortable and not tight around the penis • Holds only a small amount of urine 
Bakane Incontinence Control Device UroMed LLC		• Ratcheting plastic and rubber device • Has a push button mechanism for adding pressure to the urethra to stop leakage • Depressing the button or squeezing the sides allows voiding to occur	• Does not need to be removed during voiding, just needs to be loosened • Has the ability to fit multiple penis sizes with the plastic ratcheting sleeve
Baumrucker Incontinence Clamp Greenwald Surgical Company		• Reusable, plastic device, constructed of a hinged frame with 3 foam internal rubber pads (2 on one side, 1 on the other) • Secured with a Velcro™ strap	• Penis is placed between the two foam pads and the hinged clamp is squeezed shut, providing a closing pressure on the urethra • Clamp only comes in one size • Each pack comes with one clamp 

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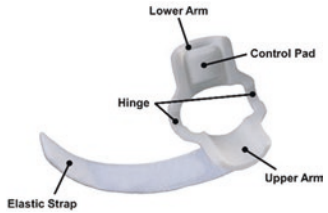
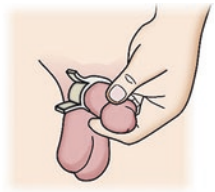
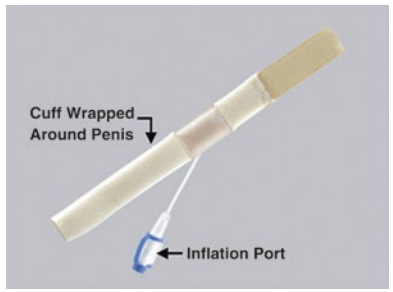
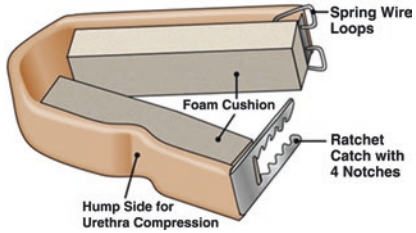
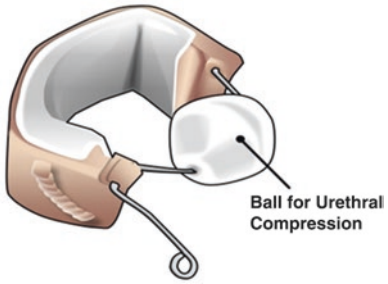
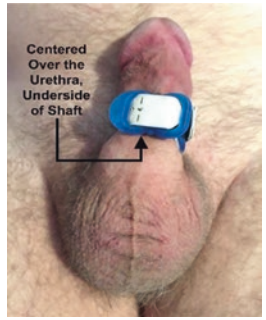
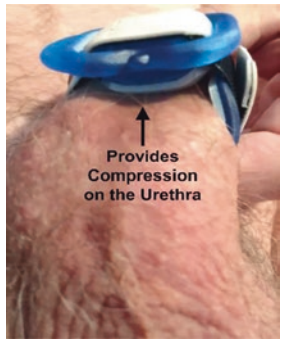
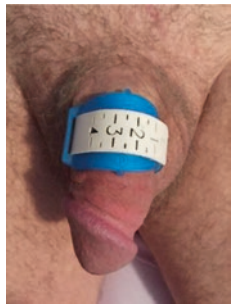
Table 7.5 (continued)

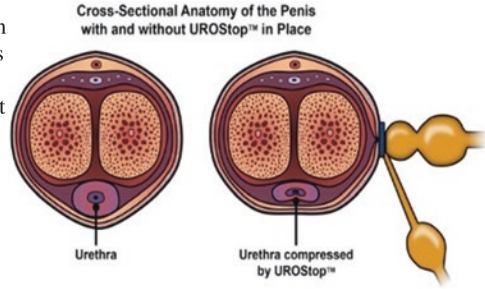
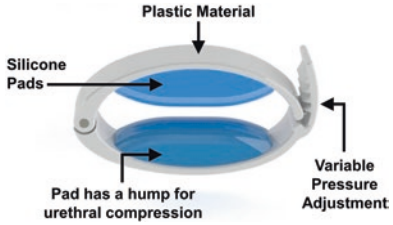
Name and Manufacturer	Device	Description	Use Considerations
Bioderm Penile Clamp Bioderm		• Plastic reusable device • Has internal foam for added comfort and a curved upper arm • Long lasting hinge designed for multiple cycles	• Designed to temporarily stop urine leakage when applying an external male catheter (see Chap. 3) • Easy use clasp, may only need *one hand* • Can be washed and reused • Designed to fit small, medium, and large anatomy
C3 Penile Compression Device Personal Medical		• Contoured plastic cradle shaped disposable device with soft foam construction and adjustable elastic Velcro™ band that adjusts the fit to provide pressure only where it is needed • Pressure is localized on the urethra by the presence of a raised control pad on the lower arm	• Penis placed through the portal between the lower and upper arms which are folded over to compress the penis. The lower arm is placed on the underside of the penis (against the urethra) • Available in regular and large sizes • Ability to operate the strapping system is often difficult for older, arthritic men • Less reliable in its ability to control leakage 
CirClamp Post-T-Vac Medical		• Circular plastic disposable clamp with soft coating and handles that are used to compress or decompress the device	• Fits over the penis by pressing the handles toward each other, then placing the clamp on the penis with the spring-loaded portion placed under the urethra for compression. • Only comes in one size, 4 in a pack • Each clamp lasts approximately 5–7 days, either until the clamp is soiled or has lost its effectiveness • Should not be washed and reused 
Cook® Continence Cuff Cook Urologic		• Inflatable device • Cuff strap is wrapped around the penis • A syringe of air is used to inflate the balloon to provide pressure on the urethra	• Easily adjustable • Not as effective in preventing urine leakage

Cunningham Incontinence Clamp C.R. Bard, Inc.		• Stainless steel hinged frame • Hump side compresses against the urethra • Clamp provides two pivoting arms with 2 foam-padded arms that compress against the penis • Employs a ratcheted latch to clamp the two arms closer together and compress the penis • Reusable	• One of the original, most commonly used and available penile clamps • Preferred by the largest number of men and associated with lowest urine loss in a trial comparing 3 penile compression devices [7]  • Requires the user to bend its compressive arms to a shape appropriate to their anatomy and then select a ratchet position to provide adequate compression. • For most patients, just the first level ratchet is needed to provide adequate leakage control • Each pack comes with one clamp. Sizes juvenile, regular or large • Common complaints are pain, swelling and penile skin break down
Dribblestop® Urine Incontinence Clamp Rennich Industries, Ltd		• Constructed of lightweight plastic with a foam cushion attached to the frame • Sculpted and shaped for flexibility • 3 in. long and ½ in. width	• Reusable clamp • The links on either side of the clamp come in 3 sizes. • Each pack comes with two clamps • Made in Canada
J Clamp JMP Medical		• Constructed of a plastic frame and barrel, stainless steel handle and axle, and a ball shaped rubber cushion that is attached to the frame and adjusted for urethral compression • The barrel compresses the urethra against a frame that fits around the sides and top of the penis	• Compact, 2 in. wide, small enough to fit through the zipper on pants • Multiple adjustable notches to create different sizes • Theoretically, the use of the barrel should have less occlusion of blood flow to the penis and potentially can be worn for longer periods

(continued)

Table 7.5 (continued)

Name and Manufacturer	Device	Description	Use Considerations
Pacey Cuff Medical Device Development Center		• Has 2 parts, the dorsal hood, which protects the circulation and the compression arm that is centered on urethra, on the ventral side of the penis • Velcro™ strap is threaded through the guide on the hood • Slide over penis and center the compression over the urethra on the underside of the penis • Has an anti-pinching flap that is designed to prevent the skin from being trapped between the dorsal and ventral parts 	• Compression should be applied firmly while the Velcro™ strap is tightened and applied to the hood to maintain the pressure • Number should be noted so that one may learn the least amount of pressure that will control urine flow  
Squeezer Klip™ Gyrx LLC		• Hinged, reusable clamp. Composed of a plastic frame with a padded top and bottom arm in a pivoting configuration • The dorsal and ventral arms include pressure-applying projections intended to contact the urethra, and preferentially apply pressure between the dorsal veins and arteries • A screw mechanism clamps the penis using a fine compression adjustment via a threaded adjustment knob • Avoids direct compression of the neurovascular bundle	• Must be able to operate a threaded adjustment knob to secure the appropriate penile compression. Patient may be incapable of repeatedly applying the pressure-applying projections to the appropriate location to effect urethral closure • The screw mechanism also requires a higher degree of manual dexterity to adjust compression, which can be difficult for older arthritic men

Uriclak Incontinence Clamp Uriclak		• One-size plastic compressible clamp without a locking mechanism • Sides of the clamp are pressed inward, the penis is inserted in the opening and the device then flattens down to compress the urethra • Spacers adjust the clamp's tightness	• Device is controlled by cylinder sets of different thickness • Is difficult for older men to apply if unable to manipulate small objects
UroStop UroSciences		• Variable tension penile loop that is used to prevent urine leakage during sexual activity (climacteric incontinence) • Latex-free	• Adjustable constriction band that is placed and tightened at the base of the penis.  • Ensure amount of tension is adequate while not causing additional problems (e.g., impede blood flow) • Should not be uncomfortable
Wiesner incontinence clamp Wiesner Healthcare Innovation		• Comes in one size (regular) • Uses silicone pads	• Center the clamp so the hump remains below the urethra • Only a light pressure needed to prevent any leakage

- Exact adjustment of pressure is achieved by several methods; such as a ratchet catch, a button mechanism, a Velcro™ strap, or a snap mechanism.
- Be sure the clamp is not set or compressed (squeezed) so tightly that it interferes with penile blood circulation.

Cleaning Instructions

Reusable clamps can be hand washed in mild soap and water and rinsed well until all soap residue has been removed. They should be air dried and not reused until completely dry. They should not be machine washed. Most of these devices should be replaced at least every month or when they show signs of tearing or cracking.

Problems/Complications/Adverse Events

Penile clamps can cause reduction in systolic penile blood flow and thus carry the risk of penile edema, urethral erosion, pain, and skin breakdown unless the penis is inspected properly on a daily basis [7, 8]. Penile clamps should only be used in men who are "cognitively intact, aware of bladder filling, have normal genital sensation, intact penile skin and sufficient manual dexterity to open and close the device" [7]. Another trial found that although clamps are more secure, associated with less UI, and less restrictive than other containment devices (external catheter, body-worn urinal), they can be more painful than other devices [9]. Pain has been reported when penile compression is sufficient to prevent urine leakage [7].

Levy et al. [10] developed a set of computational three-dimensional models of the penis and applied compression from five generic penile compression device designs. They found that the stiffness of the device's internal material affected its ability to cushion the soft tissues of the penis during external compression. The opposite was found with penile compression devices that had soft internal materials (e.g. foam). Those devices that were angled or contoured had increased contact area with the skin of the penis allowing for increased area for load transfer and more uniform distribution of internal tissue loads.

There are methods to prevent complications, including: (1) release the clamp every 1–2 hours, or sooner if there is urinary urge, and empty the bladder of urine; (2) check for skin breakdown daily when the clamp is removed, prior to bed or in the morning before the clamp is applied; (3) check the device for any breakdown or defect daily; (4) stop using the clamp immediately if there is any visible torn skin or discoloration or pain of the penis; (5) alternate the location of the clamp on the penis to avoid always compressing the same area, but do not place the clamp on the glans penis; and (6) do not wear the clamp to bed while asleep. Some patients choose to only use the device when they leave the home, or when engaging in more strenuous exercise or activity (e.g., while playing golf). This will allow more penile rest and can further prevent complications.

Evidence Base for Clinical Use

Moore et al. [7] conducted a randomized block assignment with crossover design comparing 3 different penile clamps (Cunningham clamp, U-Tex Male Adjustable Tension Band, C3 Penile Compression Device) to no device in 12 men after radical prostatectomy. They found that all 3 devices significantly reduced the amount of UI compared to no device ($p < 0.05$), but that the Cunningham clamp was preferred by men for ease of use, comfort, and least amount of urine leaked. The reduction in urine volume lost was directly correlated to the pressure of the device and limited by patient discomfort [7].

Macaulay et al. [9] conducted a randomized controlled trial comparing a sheath drainage system (external male catheter), body-worn urinal (rubber cone + flange), and penile clamp (Cunningham) in 56 men after radical prostatectomy with 1-year follow-up. Each device was tested for 3 weeks. Device and pad performance were assessed and quality of life (QoL) was measured using the King's Health Questionnaire. Intended and actual use preference for the products were also assessed. The sheath was rated as "good" for extended use (e.g., golfing, when traveling) when pad changing is difficult. The body-worn urinal was generally rated worse than the sheath and was used for similar activities, but by men who could not use a sheath due to retracted penis or because the device was not good for seated activities. The Cunningham penile clamp was found to be best for short duration vigorous activity (i.e., exercise) as it was the most secure, least likely to leak, and most discreet, but also the most painful. Pads and devices have different strengths. Most men prefer to use pads at night, but would choose a mixture of pads and devices during the day.

Mehta et al. [11] enrolled 124 post-prostatectomy patients who had climacturia during >25% of orgasms. With use of a variable tension loop (ACTIS® band, Vivus, Mountain view, CA), there was significant improvement in the degree of climacturia and QoL. At baseline, the degree of climacturia was small, moderate, and large in 16%, 72% and 12% of patients, respectively. Climacturia occurred rarely, occasionally, most of the time, or always in 15%, 48%, 16%, and 21% of cases, respectively, at baseline with use of the variable tension loop, 48% of patients experienced no climacturia. Distress was experienced by 14% and 61% of patients and partners at baseline, and 2% and 11% of patients and partners at follow-up ($P < 0.01$). This band is not considered a device for preventing urine leakage, but is used for men with erectile dysfunction who have a venous leak. A similar device, the UroStop, is discussed in Table 7.5.

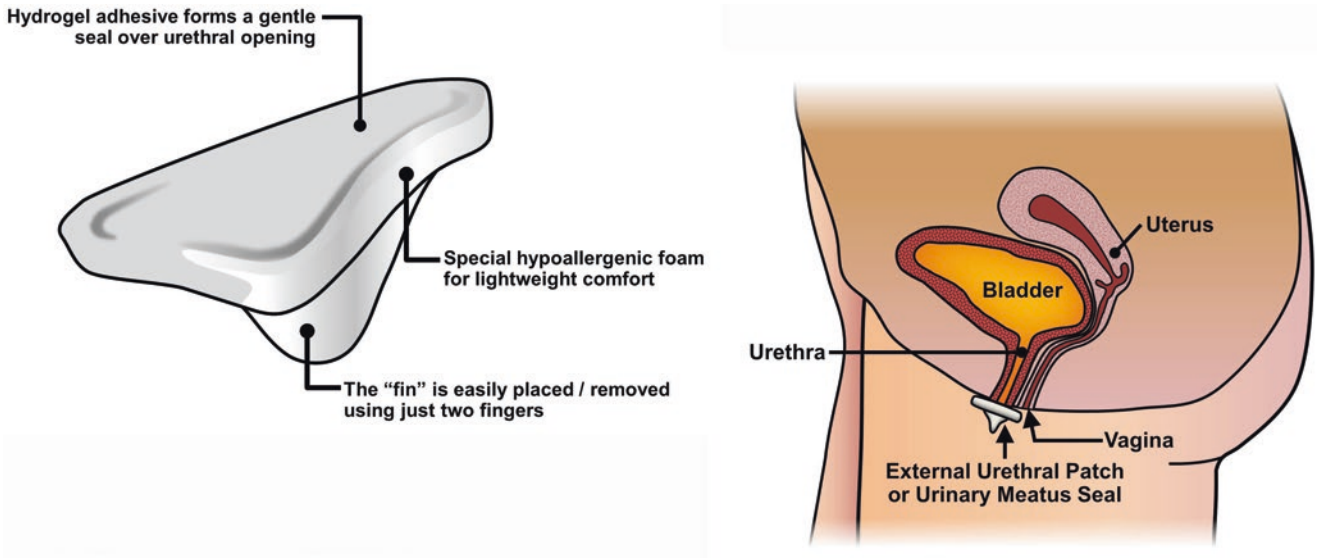


Fig. 7.12 External female urethral device—Finess™—Courtesy of Soft Health Technologies

Patient Information

General

The patient or caretaker must be shown how to properly use the clamp and be able to put it on and take it off properly before being allowed to use the clamp. Patients should demonstrate proper usage of this device in the presence of a healthcare provider. The healthcare provider should review safety instructions, emphasize the importance of leaving the clamp off during sleep or for at least 8 hours during a part of the day. The Patient Education Tool found at the end of this chapter provides information for the patient on using a penile compression device.

Product Care

Disposable devices can simply be thrown away once soiled. All of the reusable penile devices can be washed with mild soap and water when soiled. If the product contains foam, the excess water should be squeezed out, and the product allowed to air dry. Do not reapply a product that has not dried thoroughly. Penile compression devices require a prescription from a healthcare provider and are covered by Medicare.

External Urethral Device

Definition

External urethral occlusive devices (may be referred to as a meatal barrier) have been developed to block urinary leakage by creating a seal or barrier over the urethral meatus. There have been several models developed to adhere to the meatus through the use of adhesive or mild suction. The current one available is the Finess™ (previously known as the Miniguard). The Finess™ urethral barrier device (see Fig. 7.12) is a small, single-use disposable foam shield or patch that is worn externally over the urethral meatus. This barrier is held in place over the meatus by an adhesive hydrogel and is easily removed for voiding. Voiding may also dislodge the device.

Indications

The currently available urethral external device is recommended for daytime use during vigorous physical exercise in adult women with stress UI. In women with urgency UI, an external device may provide some reduction in leakage, but use in this population of women is discouraged as the external device does not have sufficient adhesive power to prevent urine leakage associated with urgency UI. If used in these women, the device will probably become dislodged during an urgency UI episode.

Material

The Finess™ is made from a material used in a number of medical applications in contact with sensitive tissue, including wound dressings. The principal component of the hydrogel adhesive is also used in other devices such as contact lenses and in permanent medical implants. The device is designed to provide a barrier at the urethral opening to prevent, not absorb, urine leakage.

Techniques/Procedure for Use

The current external meatal barrier is the Finess™ which can be purchased without a prescription from a health care provider (https://havefiness.com/). Applying the device should not be difficult for most women. The Patient Education Tool found at the end of this chapter provides information on applying on the Finess™ Barrier device. It may be helpful to have a woman apply and remove the device while observing and coaching her. In one study, the majority (62%) placed it correctly on the first attempt, 25% required a second attempt, and 13% required three attempts [12].

Problems/Complications/Adverse Events

As with any device placed on mucosal tissue, adverse events can occur. Some women may feel the Finess™, but most women, are unaware of it because the soft, flexible foam material makes it very comfortable to wear. Irritative voiding symptoms and physical signs of inflammation have been reported [12]. The device is felt to be comparable to other external adhesive products that adhere to mucosal tissue (e.g. patches).

Evidence Base for Clinical Use

Brubaker et al. [12] conducted a 20-site study to assess the efficacy and safety of the external urethral barrier Miniguard (earlier version of the Finess) in adult women (n = 346 completed study) with slight to moderate stress UI. The 21-week study period consisted of a 1-week qualifying period, 4-week baseline assessment period, 12 weeks of device use, and 4 weeks of follow-up after discontinuation of use. All subjects kept a daily journal throughout the study, recording menses and the number of devices used. The urinary leakage severity questionnaire, completed at every visit, rated the severity of leakage experienced during various activities. Thirteen activities commonly associated with stress urine loss were rated on a scale of 0–3, yielding a maximum score of 39. Subjects used an average of 4.3 ± 2.3 barriers each day at week 9, 4.1 ± 2.1 barriers at week 13, and 4.0 ± 2.4 barriers at week 17. The device was worn an average of 9.2 ± 5.1 hours per day at week 9, 9.2 ± 5.0 hours at week 13, and 9.0 ± 5.3 hours at week 17, with no statistically significant difference at the 0.01 level (P = 0.037). The Miniguard barrier device was found to be efficacious as subjective reports of urinary leakage severity fell during device use, from a baseline mean of 10.1 ± 5.1 (median 9.0) to 3.3 ± 4.0 (median 2.0) during week 9, to 3.5 ± 4.3 (median 2.0) during week 13, and to 3.5 ± 4.3 (median 2.0) during week 17 ($P < 0.001$ for all three comparisons). After discontinuing use of the device, leakage severity scores increased 7.0 ± 4.6 (median 6.0), however, control of incontinence was not complete in the majority of patients.

Intraurethral Inserts

Definition

A urethral insert is a device that is temporarily inserted into the urethra to prevent urine leakage. Usually these devices have a means to prevent intravesical migration (a tab at the meatus), a mechanism to maintain the device in its proper place at the bladder neck (e.g., balloon, fins), and a device or mechanism to permit removal for voiding (e.g., string, pump) [5]. Currently, only the inFlow™ urethral insert is available. The inFlow™ is a single-use device that requires a prescription from a health care provider. The FemSoft® [12] is no longer manufactured.

inFlow™ Control Device

Definition

The inFlow™ is an intraurethral valve-pump and activator. It is a non-surgical urinary prosthesis that pumps urine out of the bladder for women with incomplete bladder emptying due to impaired detrusor contractility.

Indications

The inFlow™ is indicated for adult women with incomplete bladder emptying due to impaired detrusor contractility of neurologic origin, who are seeking an alternative to intermittent catheterization (IC), and who are capable of operating the device in accordance with instructions or who have trained caregivers or significant others who can operate the device.

Description

The inFlow™ is a catheter-like device with four components: a sterilized, single-use urethral insert component with silicone shaft, fins, and flange; an introducer; an activator; and a sizing component (see Fig. 7.13). Under patient control, the internal activator draws urine out of the bladder when voiding is desired and blocks urine flow when continence is desired. The internal activator is opened by operating an external remote control unit [13].

Materials

The inFlow™ device has nine sizes and ranges in length from 3 centimetre (cm) to 7 cm (in 0.5 cm increments) and in diameter from 24 Fr and 28 Fr diameter. An inFlow™ sizing device is used to measure the patient's urethral length. The device is in a silicone housing and the inner valve pump consists of a

neodymium-ion-boron magnet shaped like a turbine. An internal valve and pump mechanism inserted into the urethra is opened by operating an external remote control unit (see Fig. 7.14a). The device is fixed in position at the base of the bladder by a flexible flange at the external urethral meatus. Device sizing and initial insertion is performed by a health care provider.

Technique/Procedure

The appropriate length for the inFlow™ device is determined by measuring the urethral length using a graduated indwelling urinary catheter. It may take several fittings to find a size that is comfortable and well-fitted. Insertion is similar to that for a urinary catheter. A disposable inserter is used to introduce the device into the urethra. The inserted device resides almost entirely in the urethra. The flexible silicone fins open like flower petals at the level of the bladder neck to keep the device in position. Once in place, the external flange will sit at the urethral meatus. If the patient has discomfort once the inFlow™ is inserted, rotating the device may remove possible pressure and improve comfort.

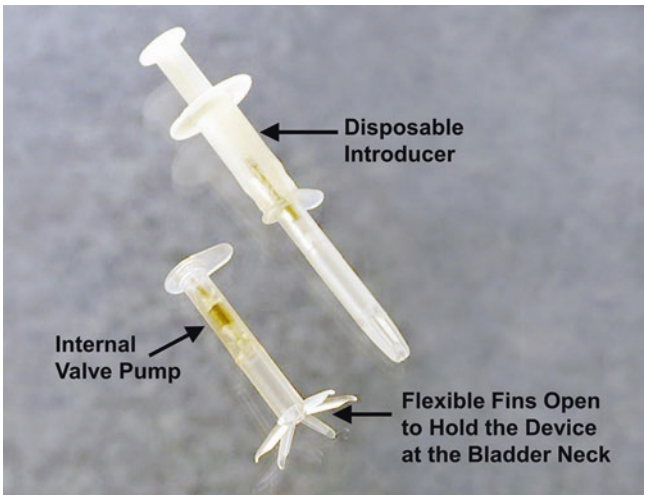


Fig. 7.13 Parts of intraurethral device (inFlow™)—Courtesy of Vesiflo, Inc.

Inside the internal valve and pump mechanism is a small magnet, which is remotely energized by the inFlow™ activator. To void and empty the bladder, the patient must operate the mechanism. The user should sit on the toilet, hold the remote control activator against the lower pelvic area (symphysis pubis), and push the "on" button (see Fig. 7.14b). The valve then opens and the miniature rotor spins at 10,000 revolution per minute (rpm), generating a urine flow of 10–12 milliliter per second (mL/s). When the "on" button is released, the activator beeps and its magnet automatically counter-spins in order to close the valve and restore continence. The activator is powered by two 3 volts (V) lithium batteries that need to be replaced every 4–6 weeks.

Each inserted component must be replaced at least once every 29 days, typically by a caregiver, the patient or a spouse. The device is easily removed by manipulating the external flange that collapses the fixation system.

Chen et al. [14] recommended that patients receive support from medical teams during the initial device-fitting phase and for the few first weeks of use.

Problems/Complications/Adverse Events

Adverse events include incontinence, urethral discomfort, frequency and urgency, UTI, expulsion, and hematuria. Table 7.6 lists these in detail. Once the patient has become accustomed to the device, discomfort and episodes of unexpected urine leakage tend to subside with continued use [14]. The position of the fins may also influence patient tolerability.

The most significant adverse event is a UTI. According to a news release by William Maisel, M.D., M.P.H., deputy director for science and chief scientist in the FDA's Center for Devices and Radiological Health, "the most significant of

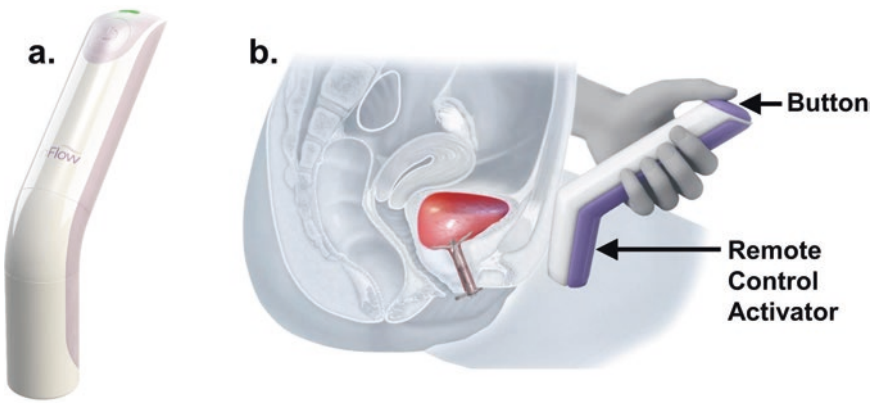


Fig. 7.14 inFlow™ female urethral insert (**a**) external hand-held remote control unit or activator operates the internal valve pump mechanism in the device, (**b**) operating the inFlow™ Device—Courtesy of Vesiflo, Inc.

Table 7.6 inFlow™ adverse events

Adverse event	Pre-existing (% of patients)	Post treatment (% of patients)
Incontinence	51	53
Urethral discomfort	3	20
Frequency/urgency	12	12
Asymptomatic bacteriuria	0	23
UTI	1	50
Expulsion	1	43
Hematuria	0	5

adverse events—UTI—appears to occur at a lower rate with the inFlow™ device as compared to CIC" http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418835.htm.

Evidence Base for Clinical Use

A multi-center, prospective, single-arm crossover study was performed to compare the safety, effectiveness, and patient satisfaction of the inFlow™ device versus IC [14]. A total of 273 women (mean age 51.3 years) were enrolled across 18 centers. Patients underwent a 1-week inFlow™ tolerability trial. Successful patients then continued through an 8-week self-catheterization phase, followed by a 16-week inFlow™ treatment phase, and a final 4-week treatment withdrawal phase. There was a large early withdrawal (N = 196) with only 77 patients completing the study, but 60 opted for post-treatment open enrollment. The most frequently reported reason for withdrawal was discomfort, followed by leakage. Mean post void residual (PVR) was comparable between baseline IC and treatment phases. There was a significant improvement in I-QOL scores after treatment ($p < 0.0001$). The authors felt that patients who were more likely to tolerate the device had lower voiding-related QOL, greater dependence on absorbent adult briefs, and were more handicapped in terms of ambulation and manual dexterity. Patients felt the inFlow™ device provided increased independence.

Madjar et al. [15] described their experience with 92 patients. There were high early and late withdrawal rates, similar to Chen's study. For those patients able to tolerate the inFlow™ device, there were very high levels of satisfaction and no significant complications.

Previous studies had examined this device with mixed results.

Schurch et al. [16] evaluated the inFlow™ device use in 18 patients, and observed a high initial "drop-out" rate of 66%, primarily due to discomfort and leakage. Clinical results were similar to Madjar et al.

An Australian study by Lynch et al. [17] of 20 patients (mean age 64.5 years) reported high satisfaction levels and an I-QOL improvement of 84% after 12 months.

Intravaginal Devices

Intravaginal devices, also referred to as "internal vaginal devices" are inserted into the vagina. These terms are used to describe a variety of devices designed to support prolapsed pelvic organs and/or support the bladder neck to improve and/or prevent stress UI. The most common of these devices is the pessary.

Pessary

Pelvic organ prolapse (POP) is seen in up to 50% of parous women [18]. These women present to pelvic floor reconstructive urology and urogynecology practices for pelvic floor muscle training (PFMT), mechanical vaginal devices (e.g., pessary) or surgical intervention.

Definition

Pessary for Pelvic Organ Prolapse

A pessary is a minimally invasive, passive mechanical device used to support prolapsed vaginal walls and the pelvic organs behind them [19] in women with symptomatic POP. Table 7.7 reviews the IUGS/ICS classification of pelvic organ prolapse. A pessary is a low risk option for treatment of POP. Guidelines recommend that nonsurgical management with a pessary be discussed with all patients with symptomatic POP, especially prior to surgical intervention [20, 21]. These devices have become more popular in the last decade, as more research has been performed on their effectiveness.

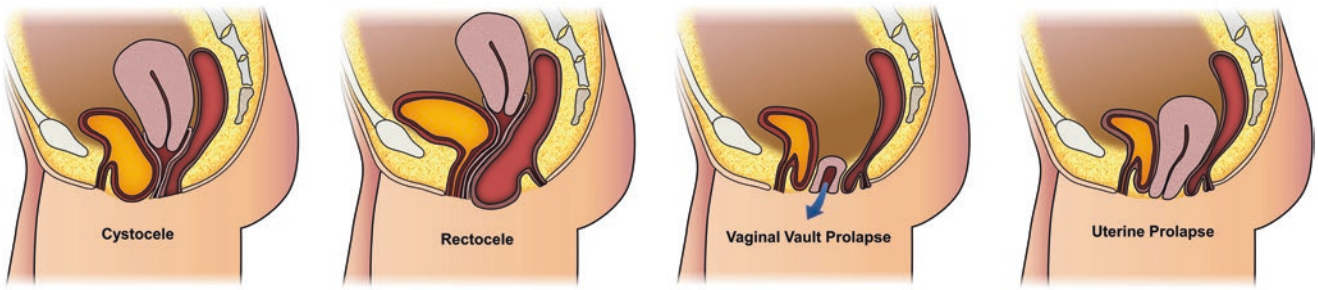
Indications

There are several common indications for pessary use, including relief of POP symptoms, a bridge to surgical scheduling or surgical avoidance, diagnosis and prediction of surgical outcome, prevention of worsening prolapse, and treatment of pregnancy complications.

The main indication for use of a pessary is to relieve symptoms of POP and it can be appropriate for either temporary or long-term use [22]. Symptoms of POP include:

- Vaginal symptoms: vaginal bulge, vaginal pressure, vaginal splinting
- Urinary symptoms: urgency, urgency UI, stress UI, urinary retention
- Bowel symptoms: difficulty with bowel evacuation, fecal urgency, fecal incontinence
- Sexual symptoms: dyspareunia.

Table 7.7 IUGA/ICS POP classification



Type of Prolapse	Description
Uterine/cervical prolapse	• Observation of descent of the uterus or uterine cervix
Vaginal vault (cuff scar) prolapse	• Observation of descent of the vaginal vault from its normal position, in women who have previously had a hysterectomy • Descent of the vaginal cuff below a point that is 2 cm less than the total vaginal length above the plane of the hymen • Upper vagina bulges into or beyond the vagina canal • Prolapse in other vaginal compartments may often occur at the same time
Anterior vaginal wall prolapse	• Observation of descent of the anterior vaginal wall • Most commonly due to bladder prolapse (cystocele, either central, paravaginal, or a combination) • Higher stage anterior vaginal wall prolapse will generally involve uterine or vaginal vault descent (if uterus is absent) • Occasionally, there might be anterior enterocele (hernia of peritoneum and possibly abdominal contents) formation after prior reconstructive surgery
Posterior vaginal wall prolapse	• Observation of descent of the posterior vaginal wall • Most commonly due to rectal protrusion into the vagina (rectocele) • Higher stage posterior vaginal wall prolapse after prior hysterectomy will generally involve some vaginal vault (cuff scar) descent and possible enterocele formation • Enterocoele formation can also occur in the presence of an intact uterus

Adapted from [70]

These baseline symptoms often drive treatment and the percent improvement experienced by patients. Patients report significant symptom improvement in short-term follow-up [23, 24]. Patients had significant improvements in health-related QoL questionnaires, Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ), but less than in patients who underwent vaginal reconstructive surgery [25, 26].

Pessary for Incontinence

An "incontinence" pessary is placed in the vagina to provide additional urethral support during increases in abdominal pressure. They are indicated for women with stress UI. They can be worn continuously or intermittently during exercise or physical activity. Both stress and mixed UI improved with a pessary in approximately 50% of women in two trials [27, 28]. The ATLAS trial found that women treated with behavioral therapy compared with an incontinence pessary had less incontinence symptoms (49% vs 33%, respectively) and better satisfaction (75% vs 63%, respectively) at 3 months, but had similar rates at 1 year follow-up [28]. The Hodge pessary or a tampon was found to be better than no treatment in a study examining urine loss during aerobic exercise [29]. However, any type of pessary that fits well and is comfortable can probably be postulated to prevent urine loss when compared to no treatment.

Additional Uses of a Pessary

Surgical Scheduling or Avoidance

Significant co-morbidities, fear of surgery, or prior failed surgery may preclude surgery for some patients. Twelve percent of providers use a pessary for a patient who is a poor surgical candidate [26]. Management of prolapse with a pessary on a long-term basis may be the optimal choice for some women. One study of 554 women undergoing treatment for POP with either pessary or surgery found similar rates of statistically significant improvement in prolapse, urinary and bowel symptoms. The only difference between the groups was an increased frequency of intercourse in the surgery group [30]. Temporary use of a pessary may improve comfort for those delaying surgery due to career or family priorities, including until childbearing is completed.

Surgical Planning: Diagnosis and Prediction of Surgical Outcome

A pessary trial prior to surgery can be invaluable in determining likely symptom improvement or the possibility of new adverse effects. This is crucial in setting realistic expectations during pre-operative treatment planning. De novo stress UI, which can occur when a deficient urethra is straightened during anterior prolapse repair, was shown to be a major reason for post treatment dissatisfaction [23], occurring in 21% of patients. Patients can then be counseled on concomitant anti-incontinence surgery at the time of prolapse repair. Prolapse may not be the cause of some symptoms (low back pain, low abdominal pain) attributed to POP, hence a pessary trial can clarify treatment expectations. A study by Heit et al. [31] demonstrated no significant association between participant-rated symptom severity and objective prolapse determination. Occasionally, patients will complain of severe bother with minimal physical findings. A pessary can be used as a diagnostic tool to assess resolution of perceived symptoms prior to surgical intervention [32]. A trial pessary of prolapse reduction was found to be a reliable tool (89% sensitivity, 80% specificity) in predicting improvement in urinary retention in women with pre-operative PVR > 100 milliliter (mL) [33].

Prevention of Worsening POP

There is some evidence to suggest a potential preventive role for pessaries. In an observational study of 90 women using pessaries for 3 months, measurement of the genital hiatus decreased, leading to the postulation that pessary use may have allowed recovery of the levator ani muscles [34]. In a small case series with only 6 patients, prolapse regressed to normal after pessary use for 27 months and remained resolved for 42 months of follow-up [35]. Whether this observed improvement is due to temporary tissue response to reduced strain or has potential long-term preventive effects is not yet clear.

Pregnancy Complications

The prevalence of prolapse during pregnancy is unknown. Pregnant women with pre-existing prolapse have a decrease in the prolapse as the uterus grows and moves out of the pelvis. But if the prolapse does not recede, then the weight of the uterus may cause further descent of the cervix outside the vaginal opening, putting the patient at risk for ulceration, infection, and urinary retention [36–38]. Pessaries have been used as nonsurgical alternatives to cervical cerclage in the incompetent cervix [39]. A lever-type pessary (Smith or Hodge) has been used to treat uterine retro-displacement that may occur in 15% of pregnancies, which can lead to uterine incarceration in the hollow of the sacrum after 12 weeks gestation (see Table 7.8). The pessary helps to displace the cervix posteriorly resulting in anteverting the uterus and allowing it to rise out of the pelvis [40].

Materials

Pessaries have been made of a variety of materials including silicone, acrylic, latex, and rubber. All modern pessaries are made of medical-grade silicone, except for the Inflatoball™ pessary. Figure 7.15 shows all types of pessaries. Silicone offers the most advantages over other materials, because it is pliable, long-lasting, non-absorbent, biologically inert, non-allergenic, non-carcinogenic, and able to be cleaned by washing or sterilization [41].

The incontinence pessary is made of the same material as those used for prolapse.

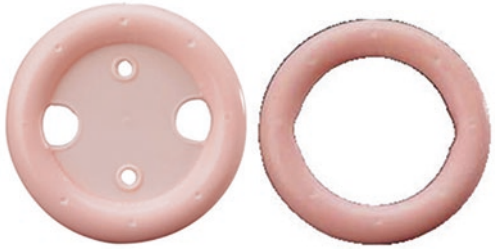
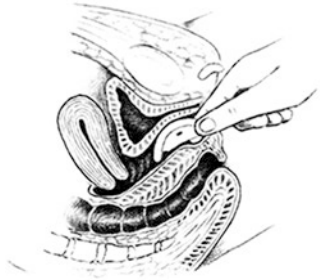
Designs

In the prolapse category, there are two basic types of pessaries: supportive (see Fig. 7.16) and space-occupying (see Fig. 7.17) [23, 39, 41]. They are detailed in Table 7.8. Pessaries come in all shapes and sizes although space occupying pessaries tend to be larger. Both types are held in place laterally by the levator ani muscles, distally by the pubic bone and the vaginal introitus, and proximally by the uterus in women with an intact uterus or the vaginal apex, in women who have had a hysterectomy. A supportive pessary is better for lower stages of prolapse (I, II, III), anterior and apical prolapse sites. Supportive pessaries include the Ring, Marland, Smith, Hodge, Risser, and Gehrung. The oval pessary is useful for a narrow introitus when a ring pessary does not fit. The patient must have good tissue integrity as these are not self-retaining. They are simpler to remove and insert than a space-occupying pessary. The ring, oval, and Shaatz pessaries are 2-dimensional and lie perpendicular to the long axis of the vagina and thus can be worn during sexual activity.

The space-occupying pessary is better for higher grades of prolapse (III, IV) and for posterior prolapse or procidentia. They have larger bases to support the vaginal apex or cervix, making them more difficult to insert and remove. This type of pessary is self-retaining and a good choice for patients with poor tissue integrity. These pessaries must be removed prior to sexual activity. Space-occupying pessaries include the Cube, Gellhorn, Donut and Inflatoball.

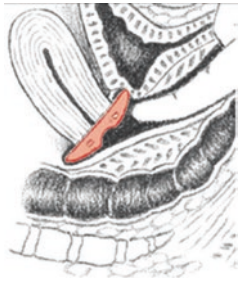
Currently, there is no evidence to support one pessary design over another. The only randomized trial that enrolled 134 subjects to compare pessary types and found no difference in patient reported outcomes comparing the ring and Gellhorn pessaries for POP [26]. A survey of the literature has found that for women with POP, ring pessaries were used 70–74% of the time, while Gellhorn or donut pessaries were used 26–29% of the time. In women with incontinence, rings or dishes were used 78–100% of the time. Clinicians rely on expert opinion, personal experience, and patient preference when selecting one design over another [39].

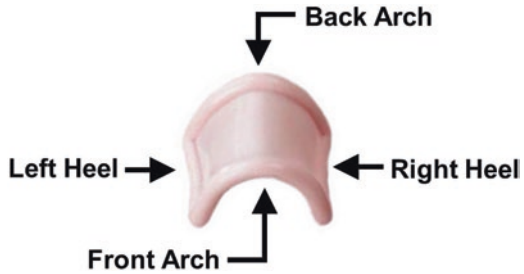
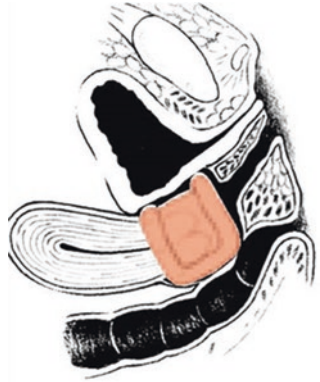
Table 7.8 Pessary types

Type	Description	Insertion	Removal
Support			
Ring with or without supportive diaphragm 	• Most commonly used pessary in this category • Easiest pessary to place and remove • Typically, the most comfortable • Commonly used sizes: 2, 3, 4, 5 in. (available in sizes 0–13) • Ring with diaphragm: indicated for mild prolapse complicated by uterine prolapse and/or cystocele • Ring without diaphragm: useful for women with mild prolapse • If the ring fails, try a Donut pessary next	• Compress the sides together by folding into a half-circle along the axis demarcated by either divot in the ring or large holes if a supportive diaphragm is present • Hold pessary almost parallel to the introitus • Direct the ring with the arc pointing downward and place pressure on the posterior vaginal wall • Use the index finger to direct the entering end of the pessary past the cervix into the posterior fornix  • Elevate the edge of the pessary behind the pubic symphysis	• With a Valsalva, hook the index finger over the leading edge of the ring • Rotate the ring at an oblique angle and pull it out through the vaginal canal • Place the hinge transversely in the vaginal canal to avoid expulsion
Oval with or without supportive diaphragm 	• Available in 9 sizes • Not as wide as a ring pessary • Commonly used for mild 1st degree uterine prolapse and/or cystocele • Shape inhibits its rotation in women with a history of vaginal surgery	• Insertion is similar to a ring pessary	• Removal is similar to a ring pessary

(continued)

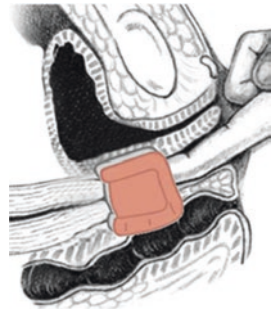
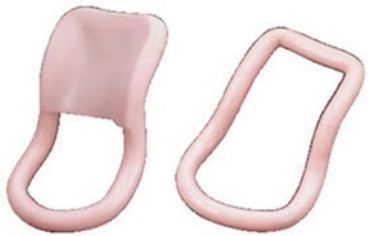
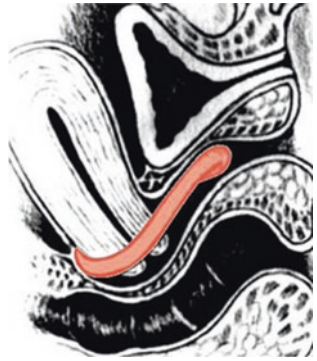
Table 7.8 (continued)

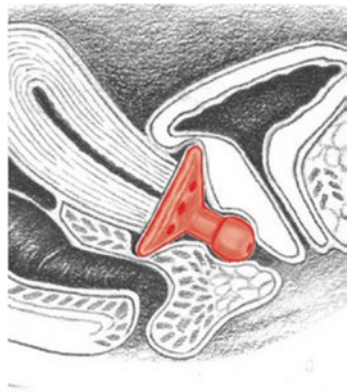
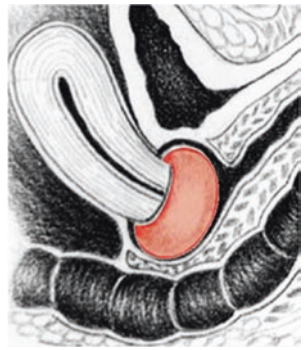
Type	Description	Insertion	Removal
Support			
Cup with or without supportive diaphragm 	• Available in 8 sizes • Indicated in 1st or mild 2nd degree uterine prolapse	• Insertion is similar to a ring pessary	• Removal is similar to a ring pessary, only hook index finger over the wedge part of the Mar-land and turn
Marland with or without supportive diaphragm 	• Similar to the ring except it has a wedge portion for additional prolapse support • Useful for 2nd or 3rd stage uterine prolapse, cystocele, and/or rectocele	• Similar to the ring • Place the wedge portion against the leading edge of the prolapse or at the vaginal opening • The ring portion should be placed against either the anterior or posterior wall	• Similar to the ring
Shaatz 	• Commonly used sizes: 2 ¼, 2 ½, 2 ¾, and 3 in. • Was formerly hard black rubber • Circular base similar to the Gellhorn without the stem • Useful in 1st or 2nd degree prolapse complicated by mild cystocele • Convex shape ensures a snug fit and center hole permits easy removal • Ideal for the patient who has a shallow pubic notch and cannot retain a ring pessary	• Does not fold but placed by inserting vertically and then rotating horizontally in place • The cervix should rest behind the disc of the pessary 	• Have the patient Valsalva and then insert one finger into the center hole to bring the pessary down towards the introitus • Then turn the rim to remove • If unable to remove with a finger alone, use a tenaculum or ring forceps to grasp the device to remove it

Gehrung (Ring arch) with support membrane 	• A concave plastic arch-shaped malleable rim with wire incorporated into the arms • Commonly used sizes: 2, 3, 4, and 5 • Derives its support from the remnants of the levator sling laterally and avoid pressure on the rectum • Used for either isolated anterior or posterior prolapse (cystocele, rectocele alone). It can be manually shaped to thin out a rectocele • May also provide relief for 2nd or 3rd degree uterine prolapse • More adaptable in cases of procidentia where the uterus tends to herniate with other pessaries • This pessary contains a wire coil and should be removed before an X-ray or MRI	 • Fold the pessary to insert it with both heels parallel to the pelvic floor, left heel first • Push the pessary past the introitus and turn the pessary by pushing the right heel back and pulling the left heel forward • Upon insertion, keep both heels of the pessary parallel to the posterior vagina with the back arch pushed over the cervix in the anterior fornix and the front arch resting behind the symphysis pubis • The arch portion faces and supports the area of prolapse either anteriorly or posteriorly • The two arches rest on the posterior vagina against the lateral levator ani muscles 	• Gehrung can rotate out of position easily • Gently push back the arch off the cervix while turning the pessary • Push the one heel forward while pushing the other heel back • Fold the pessary with the arch up, gently pulling the pessary, one heel first through the introitus, keeping both heels parallel to the pelvic floor • Squeeze the two arches together and turn the pessary to remove

(continued)

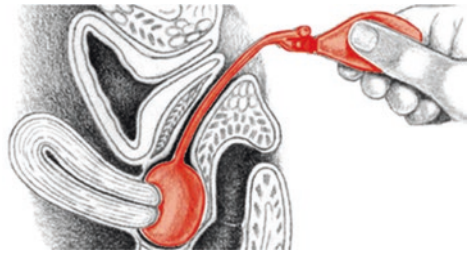
Table 7.8 (continued)

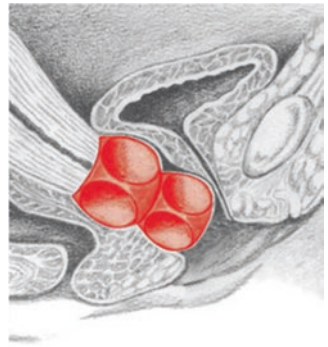
Type	Description	Insertion	Removal
Support			
Regula Folding with supportive diaphragm 	• For 1st and 2nd degree uterine prolapse • Commonly used sizes: 3, 4, 5, and 6 • Is flexible so can be molded to a better fit. The design helps prevent expulsion due to pressure from the prolapse being directly transferred in the adjusting arch of the bridge automatically spreading the heels outward • This pessary contains a wire coil and should be removed before an X-ray or MRI	• To insert, fold the pessary by bringing the left and right heels together • Use one finger of the opposite hand to press down on the perineum • Guide the pessary past the introitus and into the vagina by keeping the heels compressed. Turn the pessary by pushing the right heel back and pulling the left heel forward • The arch is positioned so that the cervix rests behind the arch • The sides of the support web will be positioned along the vaginal walls	• Similar to Gehrung • Compress the heels of the pessary together while applying downward pressure on the perineum with fingers of opposing hand and gently remove 
Hodge/Smith/Risser (Lever-type) 	• An open ring with a bend in the central portion • The shape corresponds with the curvature of the vagina • Can be used to manually antevert the uterus if it is retrodisplaced • Useful for a narrow introitus in women with 1st degree or mild 2nd mild degree stress UI and urine leakage when exercising	• Fold the device and insert it into the canal using the index finger • The posterior bar rests posterior to the cervix • The anterior bar rests behind the pubic symphysis 	• Depress the perineum, hook index finger under the anterior edge of the pessary and gently pull down

Space-occupying			
Gellhorn—Long Stem and Short Stem 	• Most commonly used in this category • Available in flexible medical-grade silicone and 95% rigid silicone • Commonly used sizes: 2 ¼, 2 ½, 2 ¾, and 3 in. • Stem comes in long (1 ½ in. from base to tip) or short lengths (1 in. from base to tip) • Concave base provides vaginal wall suction and keeps the pessary in place • Holes in the stem and base provide vaginal drainage • Indicated for advanced prolapse (3rd degree, procidentia) because it fills a larger space and less perineal support • Use the short stem version for post-hysterectomy patients • If this device fails, try a Cube pessary next	• The flexible Gellhorn can be easier to insert and remove • Separate the labia with the non-dominant hand or depress the perineum with the index finger • Folding one side of the base to the stem, insert vertically inside the vagina using a corkscrew motion • The flat disk should rest against the cervix • Once the circular base is inside the vagina, push the pessary upward until the tip of the stem is just inside and visible at the vaginal introitus (see below), low in the pelvis 	• Most difficult pessary to remove • Remove by gently pulling the stem while inserting the opposite hand beneath an edge of the pessary base to break the vaginal suction • To break the suction, you can also sweep the edge of the device with an index finger and then remove obliquely • When removing the pessary, the flat disc should be almost parallel to the introitus
Donut 	• Most uncomfortable option for patients in this category • Replaces the red rubber Donut • Commonly used sizes: 2 ½, 2 ¾, 3, and 3 ¼ in. • Size determined by width of the vaginal canal • Indicated for advanced prolapse (3rd degree, procidentia) because it fills a larger space • Should not be deflated during insertion or removal (per manufacturer)	• Some clinicians find this pessary difficult to insert • Should be compressed for insertion • Insert it vertically and, once it is placed inside the vagina, rotate it to a horizontal position • The cervix should rest behind the Donut as seen in this picture 	• To remove, hook one finger into the center hole and use the thumb and middle finger to compress the side of the Donut • Use other hand to press down on perineum to aid in removal • Bring it down and angle it until it is almost parallel with the introitus • A Kelly clamp can be used to grasp the pessary and facilitate removal

(continued)

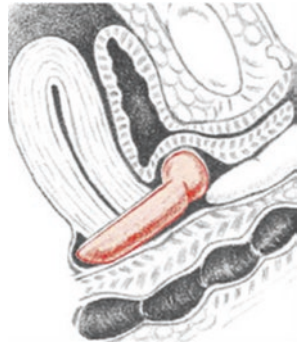
Table 7.8 (continued)

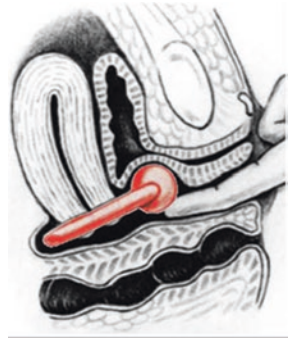
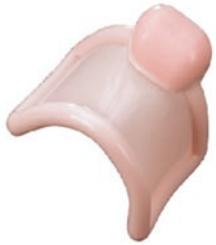
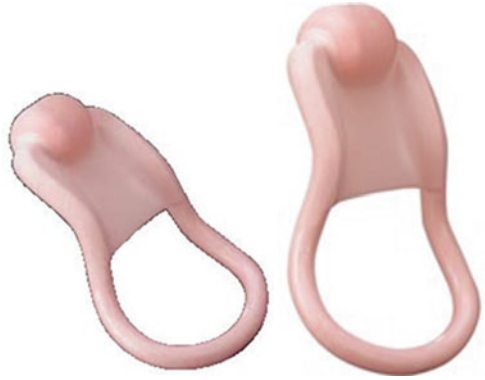
Type	Description	Insertion	Removal
Support			
Inflatable Donut (Inflatoball™) 	• Useful for high stage prolapse (3rd degree prolapse/procidentia) with or without mild cystocele and/or rectocele • Commonly used sizes: medium (2 ¼ in.), large (2 ½ in.) • Can be inserted in a narrow introitus • Air-filled ball that is inflated via an attached stem that also enables insertion and removal • Material is 100% latex • Patients may find the bulb attached stem uncomfortable	• Similar to the donut • Deflate the pessary by moving the "bead" to the closed end of the stem. Make sure all air has been removed and then attach the metal end of the bulb into the open end of the stem • Insert the deflated pessary into the vagina until only the stem protrudes • Squeeze or pump the bulb to inflate the donut (3 to 5 pumps). Avoid over inflation as it will distort and weaken latex. Any "ballooning" of the pessary indicates over inflation  • Push the small "bead" located at the tip of the stem, about ¾ in. to 1 in. forward • This should to close the air-vent and keep the device inflated • Detach the bulb and tuck the inflation stem gently into the introitus	• Must be removed after use for 24 consecutive hours or pessary can be difficult to remove if kept in place longer as negative pressure builds up, hindering the ability to break the suction, and making removal difficult • Deflate and remove air prior to removal (similar to the Donut) • Push the small "bead" down to the closed end of the stem to permit air to escape from the pessary • Grasp the deflated pessary and withdraw. Do not pull on the pessary stem as this can cause trauma

Cube with and without holes Tandem-Cube 	• Cube: Commonly used sizes: 2, 3, 4, and 5. Tandem Cube: Commonly used sizes: 3/1, 4/2, and 5/3 • Supports 2nd and 3rd degree prolapse, cystocele or rectocele, procidentia and vaginal vault prolapse • Has 6 concavities that adhere to the vaginal wall by a slight negative pressure resulting in suction • Available with and without holes for drainage • Can use a Tandem-Cube, 2 cubes fused together in a patient with a long vaginal vault, with complete lack of vaginal tonicity and if a single cube does not provide adequate support • Should be removed nightly	• Compress the device as much as possible between the thumb and forefingers and insert with downward pressure on the posterior wall towards the apex • Use the fingers of the other hand to spread the labia and guide the pessary into the vagina • Ensure the string is accessible (Tandem-Cube does not have a string) • When using a Tandem-Cube, the entering cube is 2 sizes larger than the proximal cube allowing for 10 concavities adhering by suction to the vaginal walls 	• Must be removed after use for 24 consecutive hours or pessary can be difficult to remove if kept in place longer as negative pressure builds up, hindering the ability to break the suction and making removal difficult • The cord is to help locate the Cube pessary. Do not simply pull on the string to remove the device, it will break and can traumatize the vaginal tissue • The suction with the vaginal walls must be broken to remove. Using 2–3 fingers, sweep along the edge of the device to break the suction, then grasp the edge of the cube, compress it and pull it out • Use a ring forceps if unable to remove with finger alone

(continued)

Table 7.8 (continued)

Type	Description	Insertion	Removal
Support			
Dish with or without supportive diaphragm 	• Commonly used sizes: 2–5, knob adds 1 cm to the size of the pessary • Dish with support useful for stress UI with mild prolapse and mild cystocele • Dish without support useful for stress UI with mild prolapse	• Similar to the ring with the knob inserted downward • Use index finger to situate the knob suburethrally behind the pubic symphysis at the urethrovesical (UV) junction	• Removal of incontinence pessaries involves advancing index finger, hooking it under the knob and turning it sideways for removal 

Knobbed Ring with or without supportive diaphragm 	• Commonly used sizes: 2–5 (comes in sizes 0–13) • Knob adds 1 cm to the size of the pessary • Ring with support useful for mild prolapse complicated by a mild cystocele and stress UI • Ring without support useful for stress UI	• Similar to the ring • Use index finger to situate the knob suburethrally behind the pubic symphysis at the urethrovesical junction	• Depress the perineum, hook index finger under the anterior edge of the pessary and gently pull down 
Gehrung with knob with and without support 	• Commonly used sizes: 2, 3, 4, and 5 • The incontinence knob adds ½ in. (13 mm) to the diameter • For cystocele with or without a mild rectocele complicated by stress UI	• Similar to the Gehrung • Knob should rest so that it supports the UV junction	• Similar to the Gehrung
Hodge/Smith/Risser (Lever-type) with incontinence knob without and with support 	• An open ring with a bend in the central portion and a knob for stress UI • Useful for a narrow introitus in women with mild stress UI	• Fold the device and insert it into the vaginal canal • The posterior bar rests posterior to the cervix • The anterior bar rests behind the pubic symphysis with the knob situated suburethrally behind the pubic symphysis at the UV junction	• Depress the perineum, hook index finger under the knob and gently pull down

Pessary pictures—Courtesy of Milex Products, a division of CooperSurgical and MedGyn Products Inc.

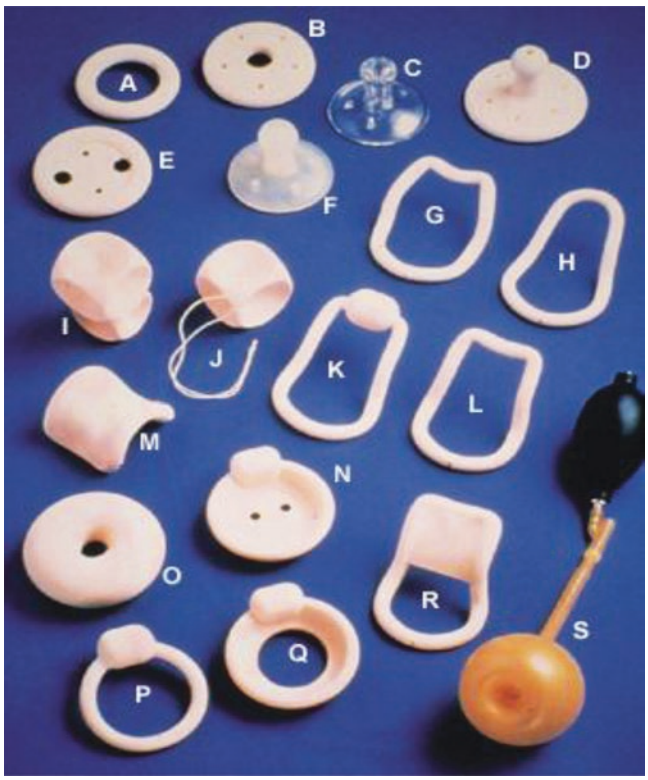


Fig. 7.15 Various types of pessaries. (**A**) Ring. (**B**) Shaatz. (**C**) Gellhorn. (**D**) Gellhorn. (**E**) Ring with support. (**F**) Gellhorn. (**G**) Risser. (**H**) Smith. (**I**) Tandem cube. (**J**) Cube with string, no holes. (**K**) Hodge with knob. (**L**) Hodge. (**M**) Gehrung. (**N**) Incontinence dish with support. (**O**) Donut. (**P**) Incontinence ring. (**Q**) Incontinence dish. (**R**) Hodge with support. (**S**) Inflatoball (latex). Courtesy of Milex Products, a division of Cooper Surgical, Trumbull, Connecticut

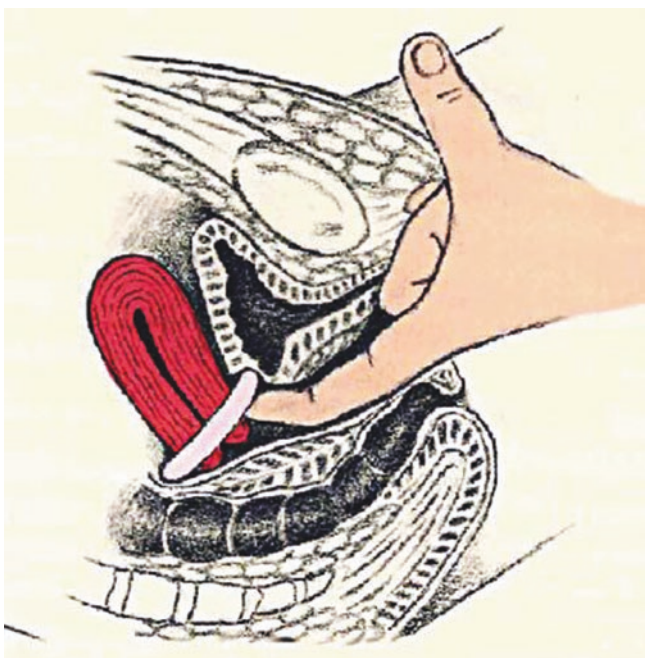


Fig. 7.16 Incontinence Ring with support—Courtesy of Milex Products, a division of Cooper Surgical

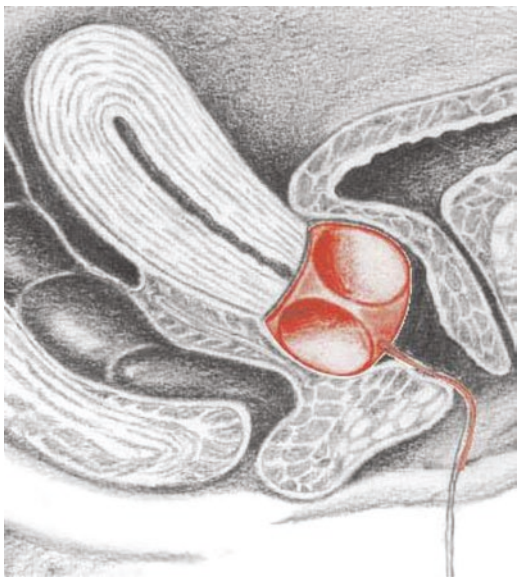


Fig. 7.17 Space occupying Cube Pessary—Courtesy of Milex Products, a division of Cooper Surgical

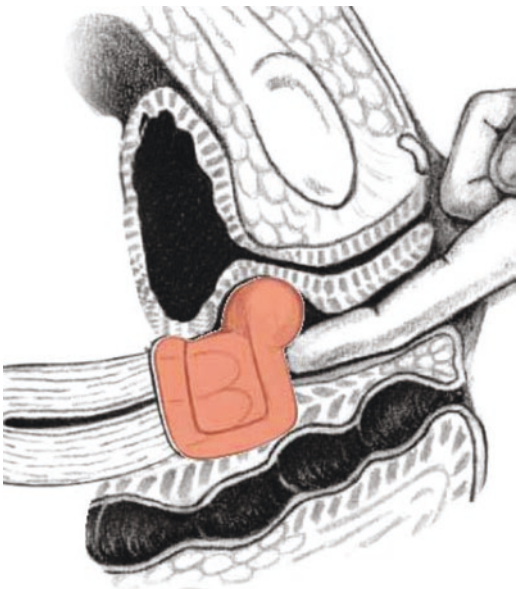


Fig. 7.18 Incontinence Pessary, Gehrung with knob against the UV junction—Courtesy of Milex Products, a division of Cooper Surgical

Incontinence pessaries have a knob on the outer rim of the pessary that once inserted, is placed beneath the urethra, increasing urethral closure pressure and, thereby preventing urine leakage (see Fig. 7.18).

Techniques/Procedure for Use

Pessaries can be fitted in most patients with POP regardless of stage or prolapse site. Sixty-three percent to 86% of

women with POP and 89–93% of women with UI can be successfully fitted with a pessary [39]. On average 2.2 pessaries are tried before finding one that fits properly [23]. It typically takes 1–2 office visits to properly fit a pessary.

Patients desiring a pessary tend to be older, have no prior prolapse surgery and have lower stage prolapse [42]. Patients desiring surgery tend to be younger, be sexually active, have stress UI, have higher stage prolapse, have posterior prolapse, and have a desire for surgery noted at the first visit [23].

Factors associated with unsuccessful pessary fitting include: (1) obesity, (2) increased parity, (3) any prior pelvic surgery including hysterectomy or prolapse repair, and (4) short vaginal length (<6 cm) or wide vaginal introitus in transverse dimension (four finger-breaths) [23, 24, 43]. Sexual activity is not a risk factor for failure. As a matter of fact, women who were sexually active were more likely to continue pessary use. This was true regardless of indication for pessary placement. Women with prolapse were more likely than women with incontinence to continue with long-term pessary use [43–45]. The steps in pessary fitting are detailed in Table 7.9.

The goals of pessary fitting are to: (1) improve targeted symptoms, (2) be comfortable, (3) be able to retain during activity and toileting, (4) not obstruct voiding or defecation, and (5) not cause vaginal irritation. Solutions to common problems or conditions when fitting a pessary include:

- Vaginal atrophy and atrophic tissue: transvaginal estrogen should be started several weeks prior to the fitting.
- Pain occurring during fitting: relieved with the application of lidocaine gel to the introitus 5 minutes (min) prior to fitting to make it more comfortable.
- Sizing challenges:
  - Pessary is expelled—a larger size should be tried until the pessary is retained.
  - Patient has pain—a smaller size will likely be more comfortable. In general, younger women require larger pessaries while older women use smaller ones
  - Weight gain or loss: refitting may be necessary.
  - Following a period of temporary removal or during long term use—epithelium may become atrophic, causing decreased support over time.
- Certain types of pessary should be used for specific conditions. Supportive pessaries can be helpful in older women, women with apical prolapse and women without a cervix. Pessaries that are going to be left in place for more than 24 hours should have drainage holes to allow continuous drainage of normal vaginal epithelial shedding and discharge.
- Expulsion of pessary: If a patient has difficulty with retaining a standard pessary size or has a wide vaginal introitus, a double pessary (Donut Gellhorn or 2 Rings or a Tandem cube) can be tried. A pessary that is comfortable and retained, except during bowel movements, may be successful if the patient is willing to remove the pessary prior to each bowel movement or support it manually during evacuation.

Follow-Up Pessary Care

Most providers recommend a follow-up appointment 2 weeks after successful pessary fitting to ensure the patient's comfort and no pessary expulsion. Long-term follow-up depends on whether the patient is capable of self-care or if the provider is removing and cleaning the pessary at regular intervals. Long-term follow-up with the provider for a vaginal exam should be every 3 months for the first year, then every 6–12 months. Motivated patients should be taught how to insert and remove their pessary. However, arthritis, mobility impairment, and obesity may limit successful self-care even in motivated women.

A survey in the UK found that 23% of the 640 obstetricians and gynecologists who responded checked pessaries every 3–6 months, 67% every 6 months, and 10% every 6–12 months. There was no difference in proportions of complications observed in 3-monthly and even up to 12-monthly observation periods. They recommend 6-month follow-up as a safe and cost-effective regimen [46].

A survey of nurse providers (323 respondents) in the US showed a range of responses in terms of pessary care. Physicians and advanced practice registered nurses (e.g., nurse practitioners) provided up to 80% of the care and 86% of the care occurred in the office setting. Care routines varied, but most often include 3-month interval follow up with speculum vaginal examinations, and no routine use of vaginal products. On-the-job mentoring was the primary knowledge source (64%) [47].

Removal and Cleaning Regimen

There is no literature to support a particular regimen for removal and cleaning. A regimen for removal and cleaning should be flexible and tailored to the patient, depending on tissue quality and ease of removal. Some patients will remove it every night, while some can remove it every 1–2 weeks.

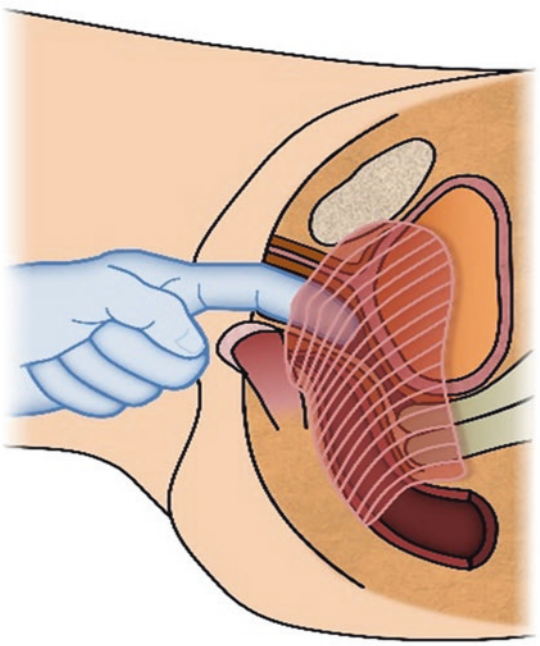
At provider follow-up appointments, the following should be performed.

1. Remove the pessary and perform a vaginal exam to assess for pessary encrustation, deformation, malfunction, or vaginal abrasions or erosions.
2. Ask about vaginal bleeding, discharge, odor, change in bowel or bladder symptoms, or abdominal discomfort.

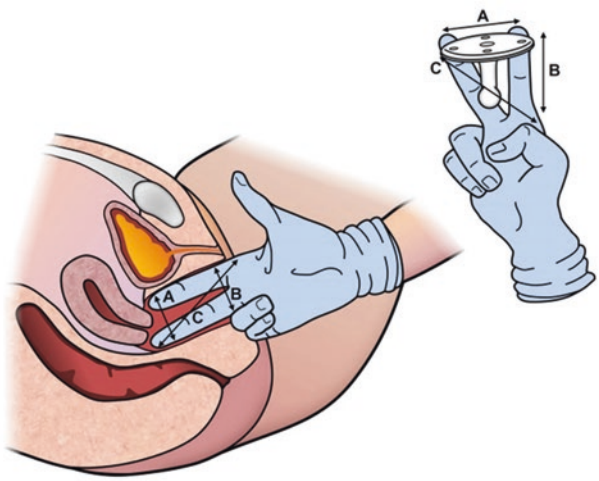
Table 7.9 Steps in pessary fitting [41]

Preparation:

- Have different types and sizes of pessaries available for patient to see, feel, and fold prior to fitting. In most cases, proper fitting will require the patient to try several pessary shapes and sizes.
- Use visual aids such as models or charts illustrations of the female pelvis to demonstrate how a pessary is used.
  o Demonstrate with a similar pessary when teaching self-care.
- Pessaries are powdered with food-grade powder so wash pessary with a mild soap, rinse and dry before initial use.
- Fitting for prolapse is more comfortable with an empty bowel and bladder, so women should void prior to fitting but, if fitting for incontinence, have the bladder comfortably full. It would be helpful to have the bowels empty, specifically the rectum.
- Place the woman in Semi-Fowler (supine with head of bed at 30 degrees) or lithotomy position.
- Perform a vaginal exam and assess for epithelial atrophy, infection, lesions, and pelvic pain.
- Reduce any high grade prolapse prior to exam or sizing.



- Perform a digital exam to assess vaginal canal length, transverse diameter, apical-posterior diameter, and PFM support.
- Have the patient perform a PFM contraction and assess muscle strength.
- When assessing vaginal canal caliber, insert two fingers to assess the diameter. Keep fingers at that width when withdrawing from the vagina. This diameter will help you select the proper pessary size. The wider the diameter, the larger the size.

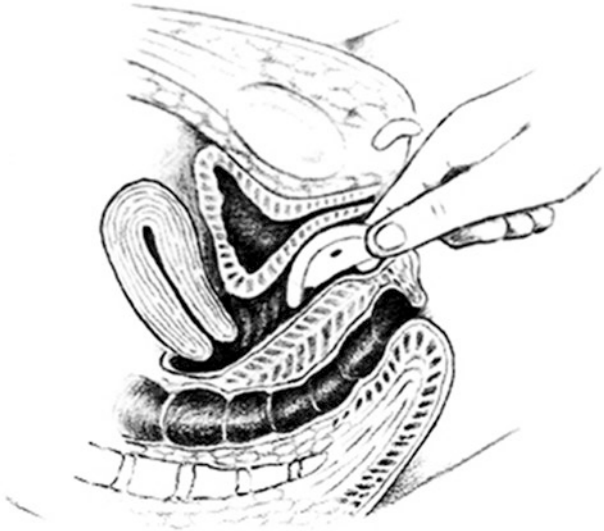


(continued)

Table 7.9 (continued)

Preparation:

- Select a common shape and size or use a fitting kit model. Wash the pessary with soap and rinse well with warm water (can make initial experience with pessary more comfortable if it's not ice cold and the pessary can be easier to manipulate when warmed).
  - Apply lubricant to leading edge of pessary (TRIMO-SAN gel can be used for lubrication).
  - Insert the pessary and apply pressure gently toward the posterior vaginal wall and/or obliquely (5 o'clock and 11 o'clock) in the largest diameter.
    - Certain pessaries (referred to as "folding" pessary) can and should be bent in order to enter the introitus and positioned in place before allowing it to expand to its full shape.
  - Avoid putting pressure on the urethra and bladder neck. The exception is an incontinence pessary.
  - Check the fit first by gently rocking the pessary in place to be sure it is not pressing too tightly on the vaginal walls. The examiner's finger should pass easily between the pessary and the vaginal wall. Then have the patient Valsalva and cough in the lithotomy and standing positions to ensure that the pessary is not expelled. If the pessary is used for stress UI, have the patient cough to test for any leakage of urine
- Test the patient's comfort and ensure the pessary is not expelled when the patient stands, walks, or bends.
  - Ask patient to sit on toilet, void, and Valsalva to simulate defecation to ensure it is not expelled. Check a PVR if necessary.
    - During this test, place a "hat" in the toilet for easy retrieval if the pessary is expelled.
    - Teach the patient to hold the pessary in place when having a bowel movement in the event that it is only expelled during defecation



Adapted from [41, 50]

3. If the patient is doing self-care, ask about ease of insertion and removal.
4. If necessary, irrigate the vagina after removal of the pessary (and before reinsertion) to cleanse the vagina of excess discharge and secretions.
5. Ensure a clinical tracking system is in place to identify missed pessary follow-up visits to avoid problems with pessary neglect.

Other Considerations

Estrogen Transvaginal Therapy

Studies have demonstrated that vaginal estrogen use results in maturation of vaginal epithelium with improvement in vaginal dryness and atrophy [48, 49]. Post-menopausal women with vaginal atrophy (now referred to as Genitourinary Syndrome of Menopause) may benefit from the use of low-dose or ultra-low dose vaginal estrogen therapy to prevent mechanical epithelial abrasion and erosion [50]. One option is conjugated equine estrogen (Premarin vaginal cream®) in 1 g or one applicator, or an amount that is the size of the fingertip to first knuckle, at bedtime for 10 days, and then twice a week. Other vaginal estrogen options include estradiol [Estrace®] and [VagiFem®]. Concomitant use of progestogen is not required for endometrial protection in women with intact uteri. However, the use of estrogen in concert with pessaries has been controversial and with limited data.

A retrospective review found that systemic and local hormone replacement therapy aided in successful pessary fitting, however there are significant side effects with systemic therapy [51]. In cases of vaginal erosion, patients are routinely treated with vaginal estrogen [52]. Another option is placing a silicone ring with a slow release estradiol (Estring®) on top of the pessary and leaving in place for 3 months. This can be exchanged at follow-up visits.

A very recent retrospective study evaluated vaginal estrogen supplementation with pessary use [53]. Data from 199 women revealed that those in the estrogen group were less likely to discontinue using their pessary (30 vs 58%) and less likely to develop increased vaginal discharge than women who did not use estrogen. However, vaginal estrogen was not protective against erosions or vaginal bleeding.

Culligan [32] did not recommend estrogen creams because of their expense, complicated regimen, and mess. It is axiomatic that the simpler the regimen, the greater the chance of adherence to therapy.

If estrogen is contraindicated (e.g., women with history of breast or endometrial cancer or those who wish to avoid any hormone treatment) or not well tolerated, regular use of

vaginal moisturizers may be beneficial in limiting vaginal discharge and odor with a pessary. However, they are unlikely to prevent vaginal atrophy or pessary-associated mechanical irritation and erosion. For women unable to use vaginal estrogen replacement due to contraindications, one applicator of TRIMO-SAN jelly one night per week can be used [23].

TRIMO-SAN (oxyquinoline sulfate 0.025% and sodium lauryl sulfate 0.01%) vaginal jelly (pH of 4.0) is recommended to restore and maintain vaginal acidity. It coats the walls of the vagina with a lubricating film that helps reduce odor-causing bacteria. Patients should be instructed to insert ½ applicatorful of the jelly three times the first week after initial insertion of the pessary, then the same amount twice a week while the pessary is in place. TRIMO-SAN is faster-spreading than a suppository and longer lasting than a douche. TRIMO-SAN has not been tested in pregnant women.

Pelvic Floor Muscle Training

The ATLAS study was a multisite, randomized clinical trial that randomly assigned 446 women with stress UI to a continence pessary, behavioral therapy (PFMT and exercise), or combined treatment [28]. Behavioral therapy resulted in greater patient satisfaction and fewer bothersome incontinence symptoms than the pessary at 3 months, but differences did not persist to 12 months.

A retrospective comparison of ring pessary to multicomponent behavioral therapy in managing overactive bladder showed similar cure rates between the two (19% for pessary, 20% for behavioral therapy). Comparable cure rates were noted in premenopausal and postmenopausal women, in women who had undergone previous treatment, and in those who had not had previous treatment. Neither treatment outcome was associated with POP quantification at the anterior and posterior vaginal wall and at the vaginal cuff; previous treatment; overactive bladder symptoms; pad usage; or any combination thereof [54].

One study of 554 women undergoing treatment for POP with either pessary or surgery found similar rates of statistically significant improvement in prolapse and urinary and bowel symptoms compared at 1 year. The only significant difference between groups was increased frequency of intercourse in the surgery group, which was not significant when controlled for age [30].

A recent randomized controlled trial showed that there was a significantly greater improvement in the prolapse symptom score in those treated with a pessary versus PFMT, although there was a nonsignificant difference in the primary outcome, that is the change in pelvic floor symptoms (PFDI-20 score) [55].

Sexual Activity

A pessary can be used in sexually active women and may either be removed or left in place. Women who leave the pessary in place are likely to find the Ring or Oval to be the most comfortable.

Menstruation

Some women will choose not to wear the pessary during menstruation while others—especially those with the ring—will continue to use tampons. Menstruation will cause the pessary to become discolored more easily, but it does not affect its use. A pessary should be replaced when it becomes cracked or loses shape or strength. There is no need to replace for discoloration.

Continued Pessary Use

For those with POP, factors associated with continued pessary use include sexual activity, older age, (the highest predictor), and poor surgical risk [44]. A cross-sectional study of 78 women showed that predictors of unsuccessful pessary fitting (42%) were age, body mass index, and having underactive PFMs [55].

For incontinence, factors that favored continued pessary use include pulmonary disease and use of diuretic medication [27].

Causes for Pessary Discontinuation

Some women may experience bothersome new symptoms during a pessary trial. These can include problems with bowel and bladder emptying, pressure, and pain. There may be an increase in vaginal discharge or odor. There can be onset of stress UI, because the kink in the UV junction has been straightened by the pessary unmasking occult stress UI.

Clemons et al. [23] reported that the most common factors for dissatisfaction included de novo stress UI, strong desire for surgical treatment, and more advanced prolapse (stage III or above).

Contraindications/Problems

Contraindications

There are a few absolute contraindications to pessary use. These include any condition that would predispose an individual to neglect of a retained pessary, such as dementia or noncompliance. Any exposed foreign body, such as vaginal mesh, must be resolved before using a pessary. Latex sensitivities are less of an issue given that most pessaries are now made of silicone (except for the Inflatoball™). An active vaginal infection will need to be treated before starting or resuming pessary use.

Vaginal atrophy can be considered a relative contraindication. Most providers would advise the use of transvaginal estrogen therapy prior to pessary use in women with vaginal atrophy. Some providers feel that using a pessary can actually help manage erosions and facilitate healing with close follow-up [26, 41].

Problems

Vaginal abrasions are more commonly seen in women with vaginal atrophy and can be treated with daily estrogen cream and weekly follow-up. Frequency of local estrogen therapy can be decreased if healing is progressing. Once healing is complete, the pessary can be fitted or restarted.

Vaginal discharge and odor can be treated by more frequent removal and cleaning of the pessary. Discharge and odor is relatively common in those who do not perform self-care. The pessary can trap secretions caused by desquamation, which break down and cause increased creamy discharge and odor. A pessary with drainage holes can allow better drainage in such cases. Acidification of the vaginal pH may restore the pH balance of the vagina. Atnip [39] suggests a monthly douche with water, plus a small amount of vinegar. Others recommend the use of a gel to maintain vaginal pH (e.g., TRIMO-SAN jelly).

If estrogen is contraindicated or not well tolerated, regular use of vaginal moisturizers may be beneficial in limiting vaginal discharge and odor with a pessary. However, they are unlikely to prevent vaginal atrophy or pessary-associated mechanical irritation and erosion.

Bacterial vaginosis occurs in 32% of women with pessaries. The pessary should be removed 10 days prior to any vaginal surgery and bacterial vaginosis should be treated if present to prevent infectious complications.

UTIs occur in 13% of women with pessaries. Vaginal estrogen treatment can aid in improving vaginal mucosal integrity, normalize vaginal pH, and promote lactobacillus growth—all factors that can decrease the frequency of post-menopausal UTIs.

Women using pessaries can have abnormal PAP smears due to inflammation. These changes were found to completely reverse with removal of the pessary and use of estrogen cream [56]. Some providers recommend removing the pessary 1–2 weeks prior to scheduled PAP smear testing [32].

Complications/Adverse Events

Major complications and/or adverse events from a pessary are rare but have been reported. Vaginal erosion/ulceration is a serious complication. Signs of erosion include heavier and more odiferous vaginal discharge. Patients typically cannot feel an ulcer, so inspection of the vaginal vault at each visit is essential. Ulceration rates vary between 2% and 24% [23, 43, 51]. The ring pessaries in these studies were less likely than the Gellhorn or cube to cause erosion, and erosion was less likely in women performing self-care. Cube style pessaries were associated with more vaginal erosions than ring styles in the study by Wu et al. Erosion is often treated by removing the pessary for several weeks and using estrogen vaginal cream nightly. After healing, the provider should determine whether the pessary is the correct size and type.

One surgical complication that can occur is a fistula. In a review of the literature from 1950–2007, 39 major complications requiring surgical intervention were identified. These included 8 vesicovaginal fistulas, 5 urologic complications, 4 rectovaginal fistulas, 3 bowel complications, and 19 impacted pessaries. All cases were related to Gellhorn or Gellhorn-like pessaries. All but two occurred due to pessary neglect [57]. This emphasizes the importance of regular follow-up.

An additional complication can be an impacted or neglected pessary, which is one that has been in place for an extended amount of time without any care. These can cause pain, vaginal erosion, and fistula formation [58].

Evidence Base for Clinical Use

There has been a lack of randomized clinical trials evaluating pessaries for both POP and incontinence. Therefore, the Cochrane review in 2013 on Pessaries for Pelvic Organ Prolapse in Women [19] only resulted in one randomized controlled trial that met inclusion criteria. This is the PESSRI study, which is a randomized multi-center trial with a crossover design that utilized standardized validated clinical questionnaires for POP and standardized clinical staging with POP-Q [26] to evaluate symptom relief outcomes between the Ring and Gellhorn pessaries. The study showed that both pessaries were effective for the approximately 60% of women who completed the study with no significant differences identified between the two types of pessary.

Since then, Panman et al. [55] reported on the effectiveness of pessary treatment compared with PFMT in older women with POP in a two-year follow-up of a randomized controlled trial. This showed that pessary treatment had a significantly greater improvement in the prolapse symptom score than those treated with PFMT, although there was a non-significant difference in the primary outcome which was the change in pelvic floor symptoms (PFDI-20 score). Direct medical costs over the two year study were $309 per person for pessary treatment and $437 for PFMT.

A recent systematic review [59] assessed the impact of pessary use on the QoL of women with POP. All articles associated pessary use with improved QoL based on validated questionnaires, including improved urinary and bowel symptoms, and sexual function. The satisfaction rate was 59% (range 45–70%). The discontinuation rate was 49%, with reasons including failure to retain the pessary, discomfort, a desire for surgery, and an inability to insert or remove the pessary. More than half of women using a pessary continued to use the device.

Patient Information

Teaching Tools and Education

Patient acceptance of a pessary and other intravaginal devices depends on counseling and education. Patients often need reassurance regarding placement and are concerned that it will get "lost" or be placed in the wrong position. When patients feel their own pessary, they often feel it just inside the introitus. However, many visual aids show the pessaries located at the apex. This can lead to patient confusion about the proper position of the pessary and whether or not it is located in the correct place.

Other Vaginal Support Devices

Definition

There are other devices that are placed in the vagina to support POP or control incontinence, with different mechanism of action, materials and designs than a pessary. Vaginal support devices discussed in this section include the Colpexin™ sphere, the Impressa®, and the Uresta®.

Indications

- *Colpexin™ sphere* is a removable and reusable intravaginal device designed to reduce POP while positioned above the levator ani muscle and to enhance the performance of PFM exercises [60]. It is available only by prescription.
- *Impressa®* is an over-the-counter intravaginal device for women over the age of 21 with stress UI. It is manufactured by Kimberly-Clark under the Poise absorbent product brand.
- *Uresta®* is an intravaginal support to control mild stress UI. Currently, it is only available for purchase online or in pharmacies in Canada. Depending on the region, it may or may not require a prescription.

Materials/Designs

- *Colpexin™ sphere* consists of a smooth medical-grade polycarbonate sphere with an attached braided string (Fig. 7.19). By elevating the prolapse defect, it facilitates the performance of proper PFM exercises. It is designed by Adamed, Inc. of Rutherford, NJ (the US subsidiary of the Warsaw-based company). It is available in five sizes (32, 36, 39, 42, and 44 mm). It received FDA approval in May 2004.
- *Impressa®* (see Fig. 7.20) is a disposable tampon-like device that comprises a core, cover, and applicator. The core is made of medical-grade silicone, composed of flexible anchor and support poles made of resin. It is designed

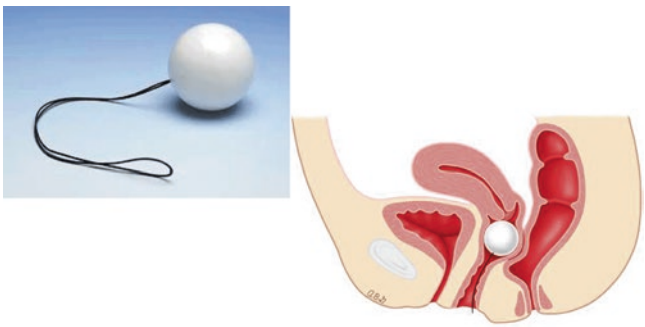


Fig. 7.19 Colpexin™ sphere intravaginal device

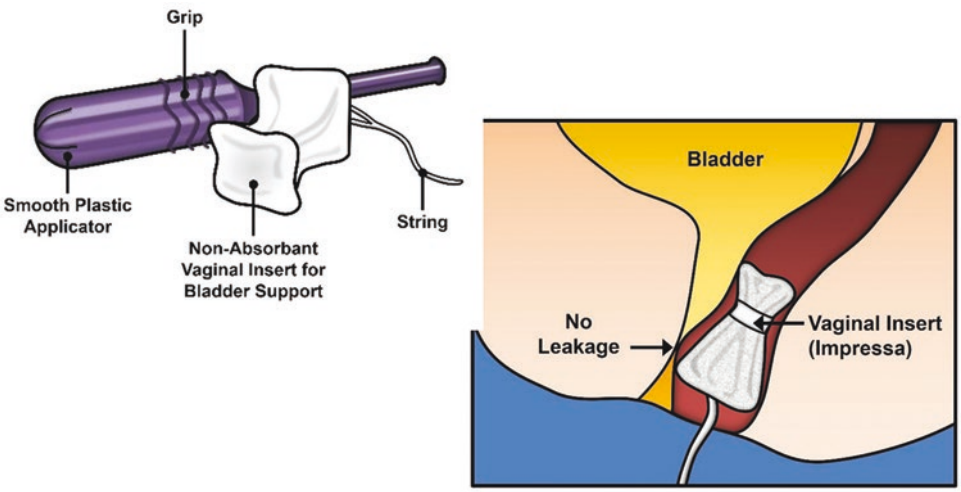


Fig. 7.20 Impressa® intravaginal insert

to prevent the device from moving within the vagina and to produce sub-urethral tension-free support whenever pressure is transferred from the abdominal cavity to the pelvic floor. The cover around the core is made of soft, biocompatible, nylon mesh that stretches between the arms of the support poles to act as a tension-free sling without obstructing urinary flow or vaginal secretions. A polyester and rayon string is attached to the distal end of the cover for removal of the device. The core and cover are preassembled within a smooth, small diameter plastic applicator, similar to those used for tampons, which allows for insertion directly into the vagina. It comes in 3 sizes (1, 2, and 3). Size 1 has a base width of 1.5 in., and sizes 2 and 3 have a base width of 2.0 in. (see Fig. 7.21). While size 2 and 3 have the same width dimensions, size 3 provides the most support. It is not absorbent and should be removed during menstruation.

- *Uresta*® (see Fig. 7.22) is bell-shaped, with a narrow tip that allows for easy insertion into the vagina in a similar fashion to a tampon. Its shape causes it to exert a small amount of pressure on the vaginal wall, which in turn supports the urethra. It is made of a non-absorbent hypoallergenic thermoplastic rubber approved for medical use. It contains no rubber latex. A complete set (see Fig. 7.23) includes three sizes (size 3, 4, and 5) that can be fitted by a healthcare provider or by the patient. In Canada, the Uresta® was voted the Adult Care Incontinence Product of the Year in 2016.

Techniques/Procedure for Use

- *Colpexin*™ *sphere* must be fitted for each woman based on size and degree of prolapse and the underlying PFM tone. When inserted correctly, it sits within the vaginal canal above the levator ani muscle. It is self-inserted into the vaginal vault with an applicator or by hand.

The patient should be instructed to perform PFM exercises at least twice a day while wearing the sphere [61]. With the device in place, the patient should lay in a semi-recumbent position, contract or tighten the muscles around the vaginal opening, and feel for a lifting of the Colpexin™ sphere and closure of the vaginal opening. The patient then locates the string on the device and gently pulls on it, so they can feel that the sphere is in the correct position, above the PFMs. Then, the patient should relax their muscles. The patient gradually increases the hold time of each contraction to 3–5 seconds (s) and relaxes for 3–5 seconds, with the goal of 10 seconds contractions for ten repetitions. The patient should always relax the PFMs for an equal amount of time between contractions. The quality of the exercise is more important than the number of repetitions or length of hold. Instruct the patient to avoid straining, holding her breath, or using her buttock muscles. As the PFMs become stronger, the patient can challenge herself by gently tugging on the string while tightening the PFMs. Don't pull so hard as to cause the device to come out.

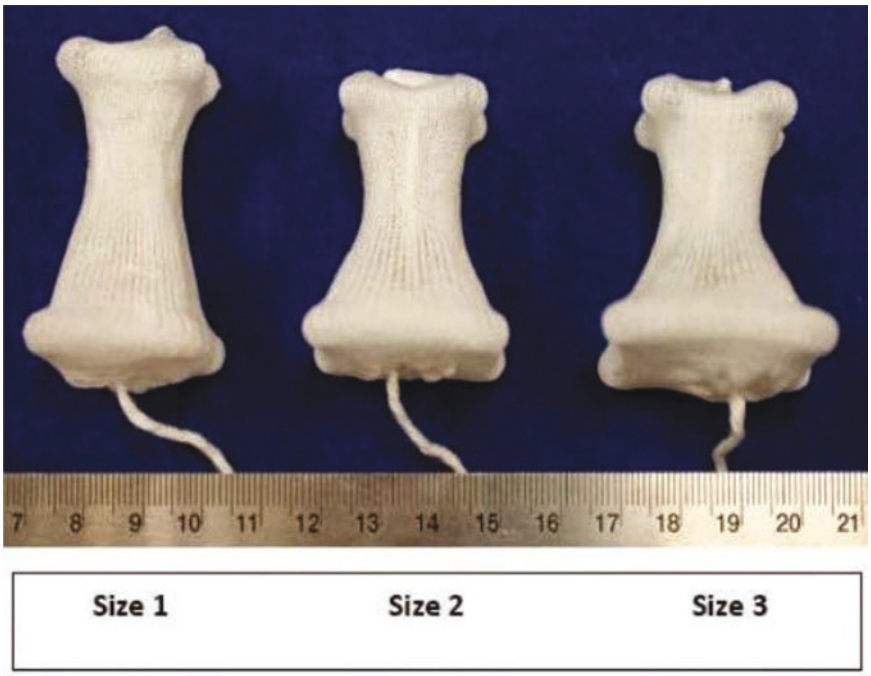


Fig. 7.21 Sizes of the Impressa® intravaginal insert

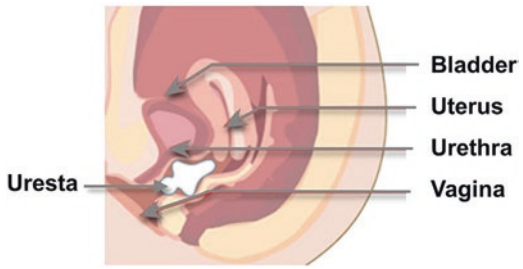


Fig. 7.22 Intravaginal device in position in the vagina-Uresta®

Fig. 7.23 Uresta® Intravaginal device

- *Impressa*® has a sizing kit that the woman follows to find the correct size. Start with size 1. The device is inserted similar to a tampon, with the applicator inserted into the vagina and the plunger pushed all the way into the applicator until it stops. This deploys the device. The support should be about ¾ in. inside the vagina (up to the first joint of the pointer finger). The removal string should be hanging outside the body. If the device feels comfortable and the patient has little or no leakage, then size 1 is correct. If there is continued leakage, then move on to try the next size. It can be used for up to 8 hours each day.

  The device provides added support to the urethra but does not obstruct it. It does not need to be removed before urination or defecation. It is disposable and for one time use only. Patients can apply a water-based lubricant to the tip of the applicator if vaginal atrophy causes discomfort with insertion. It will need to be removed before sexual intercourse. It is not absorbent, and should be removed during menstruation.
- *Uresta*® does not require provider fitting or insertion. The patient can check the sizing guideline and self-insert. The smallest size should be is placed first, and the patient should cough or perform routine activity that typically causes UI. If leakage is still present, the next size should be used; until there is no leakage, the largest size is reached; or the patient is uncomfortable due to the size. It can be used for one year before replacement. It does not need to be removed for urination or defecation. If the patient is unable to urinate or defecate, she may need to decrease the size of the device used. It needs to be removed for sexual intercourse. The Uresta® should be hand-washed with mild soap, rinsed well, and allowed to air dry in its case.

Problems/Complications

- *Colpexin*™ *sphere* problems can occur with short-term use. Reported problems with urination (29%) and defecation (72%), primarily due to device displacement. Two of 39 patients developed superficial vaginal mucosal ulceration which resolved spontaneously in a prospective multicenter clinical trial [62]. In a randomized controlled trial of 85 subjects evaluating Colpexin™ and PFME versus PFME alone, 85% of participants experienced vaginal discomfort, were aware of a lump in the vagina or felt the vagina was too loose. Two patients reported heavy vaginal discharge, one reported vaginal discomfort and one reported lower abdominal discomfort [63].
- *Impressa*® is not indicated in women under the age of 21, who are pregnant, have had unusual vaginal bleeding within the last 6 months, have symptoms of a UTI or vaginal infection, have had vaginal surgery within the past 3 months, or have non-stress UI.

  In an open-label, controlled, two-center study, 60 women were recruited to test the device for 28 days. Urinary flow rates and PVR volumes were not significantly changed. PVR volumes were 14.5 mL pre-study compared to 17 mL during device usage. There were 27 cases of vaginal discomfort, 15 cases of vaginal pain, 14 cases of vaginal spotting (mild), and 1 case of candidiasis. There were no vaginal excoriations, sores, ulcers, scratches, or any signs of inflammation on vaginal exam [64].
- *Uresta*® has had no adverse events or complications reported in two studies.

Evidence-Base for Clinical Use

- *Colpexin*™ *sphere*: In the first study to evaluate the safety and effectiveness of Colpexin™ sphere, Lukban et al. assessed the efficacy by a baseline versus 16-week comparison of POP staging and PFM strength assessment. Subjects also completed a patient satisfaction questionnaire. Improvement in the prolapse of at least one vaginal segment was seen in 81.5% of the patients, while 63% exhibited improved muscle function on digital exam at 16 weeks. Ninety-three percent would recommend the device to treat prolapse, and most found it easy to insert and remove [62].

A single blind, randomized controlled trial was performed recruiting 91 patients with 85 completing the study. It compared Colpexin™ sphere and PFM exercises versus PFM exercises only for 16 weeks. Patients were asked to perform the PFM exercises three times a day, with ten repetitions each time, holding and relaxing for 10 s intervals. Patients were examined at baseline and at 16 weeks by two providers who were blinded to the participant's group. Quality of life was measured using the Thai-version ICIQ vaginal symptoms questionnaire. There was no significant difference between the two groups. Vaginal symptom score decreased in both groups while the stages of prolapse did not change [63].

- *Impressa*®: In the open-label, controlled, two-center study, 60 women were recruited to test the Impressa® for 28 days. The primary endpoint was the percentage of women who achieved a >70% reduction in PWG from the control period to the last 14 days of device usage. All women had severe stress UI based on pre-study urodynamic study. Eighty-five percent of participants achieved a >70% reduction in PWG. Mean PWG decreased from 17 g/8 hours to 2 g/8 hours a mean percent reduction of 86%. All women reported feeling urine leakage during the control period, whereas only 8% felt urine leakage at the end of the study. A high degree of satisfaction was reported. Ninety-two percent of the women reported a QoL improvement of 10%, 88% reported a QoL improvement of 50%, and 70% reported a 90% improvement [64, 65].
- *Uresta*® An uncontrolled study of 21 women showed the device significantly reduced UI measures, with no reported complications. A 47% reduction in self-reported stress UI symptoms was demonstrated and pad weight showed a 50% reduction in leakage. Among women successfully fitted, 76% continued using the device at one year [66]. A very recent single blind, randomized controlled trial of the Uresta enrolled 36 subjects, 18 in the Uresta arm, and 18 in the placebo vaginal silastic ring arm. The percentage of patients who achieved the primary outcome of a 50% or greater reduction in pad weight was 66% in the Uresta® group and 22% in the placebo group. There were no adverse events or patient reported discomfort. However, this was an extremely short-term study, performed in a single site [67].

Toileting Assistive Devices

Definition

Mobile or hand-held containers and devices, often referred to as "portable toilet substitutes," can be used by individuals to collect urine instead of the fixed toilet in the bathroom. There are two general categories: one including commode seats or bedside commodes, and the other including hand-held devices such as a bedpan or urinal (see Figs. 7.24 and 7.25). They are described in Table 7.10. A female urinary device (www.freshette.com) used by women in the military is a portable lightweight palm-sized funnel that has a 6-in. retractable spout (see Fig. 7.26) [68].

Toilets

Adequacy and availability of bathroom facilities, including number of toilets, is important for many urologic patients, especially those with voiding dysfunction, UI, and so on. The height, location, and width of the toilet are all important. To increase height, raised toilet seats (referred to as toilet raisers) placed over a regular toilet allow the individual to get up and down independently, allowing for self-toileting and adequate voiding. A toilet seat that is a different color from the floor may be helpful for patients with visual impairments.

Fig. 7.24 Female urinals

Fig. 7.25 Male urinals

Table 7.10 Toilet substitutes or assistive toileting devices

Product/device	Description	Considerations
Hand held (urinal, bedpan)	• Male and female urinals have a variety of designs, can be disposable or reusable, and some are better in certain positions (e.g., standing, sitting) ○ Women: are available in a variety of shapes and sizes incorporating an interfacing opening that is often anatomically shaped to fit snugly against the woman's body. ○ Men: vary less in design, have a narrow neck opening to accommodate the penis, and some are fitted with integral non-spill valves or adaptors to prevent the back-flow of urine following use • Usually made from molded plastic • Some are equipped with handles to facilitate positioning and handling, and some are fitted with drainage bags to collect urine. • Rehab urinals with large funnel openings are available for men with a retracted penis. These urinals have a flat bottom so that they can lie flat on the bed • A fracture bedpan is a better alternative for females in wheelchairs or those who are bedbound, as this type of bedpan has a slanted end that allows for easy sliding and positioning under the perineum	• In men, who have hemiparesis or poor manual dexterity or spill urine when removing the urinal, consider a urinal with a spill-proof opening and a flange that extends into the urinal or one with a spill-proof valve as these prevent backflow, even when held almost upside down. • Occupational therapists can assess patients as to appropriateness of a urinal • Aids in being able to urinate without pain • Fracture bedpan promotes voiding, especially in the post-operative patient who is unable to ambulate (e.g., following a fracture or bone replacement), but is generally the least-effective container, as it is difficult to position without creating excess pressure on the sacral area • Small, discrete, disposable and re-useable 'travel' handheld urinals are available for both men and women
Urine director/ collector	• Small portable devices that are designed to primarily help women pass urine in a convenient place, in particular when standing up • Are either cardboard or plastic and designed to be thrown away after each use or are plastic/latex and designed to be washed and reused	• Do not have any storage capacity • Women in wheelchairs, after positioning themselves in front of the toilet, can use a funnel-shaped device that fits against the vulva area and channels urine into the toilet (see Fig. 7.27) • Particularly useful when travelling or when access to a toilet is difficult. Most will fit in a small bag or pocket
Commodes chairs	• Portable toilet that can be placed next to a bed for nighttime voiding or in any room to improve toileting access • Many different commodes exist that can ease toileting. Some have drop arms and adjustable heights to allow for tailoring the commode to the person's needs. Other commodes are backless and can be placed on a toilet for quick adaptation in a bathroom	• Consider the following: ○ Height and weight of the person using the commode ○ Mobility and dexterity, especially if the person will need to empty and clean the commode ○ Cost, as most insurers will pay for at least one commode per person with a letter of medical necessity ○ Type of seat, as a plastic seat with a large soft surface area may allow even distribution of body weight ○ Seats with grab bars on either side, recommended to prevent falling and to aid with rising ○ Problems with commode design, including difficulties with sideways transfer; ineffective brakes causing commodes to move during transfer; and poor trunk support

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Fig. 7.26 Female Urinary Voiding Device Freshette, International Sani-Fem, Inc.

Fig. 7.27 Bottom Buddy™ Toilet Tissue Aid

Other Toileting and Personal Hygiene Aids

For many urologic patients, personal hygiene, and particularly perineal hygiene, can be a challenge. In addition to urinals and bedside commodes, other products and devices are available to help with this issue.

Toilet paper wiping aid is an ergonomically designed wand-type plastic device that is curved and approximately 11 in. to 20 in. in length (see Fig. 7.27). It can make toileting easier for any individual unable to reach their perineum to complete personal hygiene after urinating or defecating. This simple device can help a person keep their independence and dignity with toileting. One end grasps toilet paper or wet wipes and reaches the perineum to help patients clean after toileting while the handle end allows the user to eject the paper or wipe after use. The release button drops soiled tissue into the toilet. The device can be cleaned with soap and water as needed. Some include a carrying case or bag. Several brands include Bottom Buddy™ Toilet Tissue Aid, Buckingham® EasyWipe Wiping Aid, Comfort Wipe, FreedomWand® Self-Wiping Aid, Juvo® Self Assist Toilet Aid, and Self Wipe® Bathroom Toilet Aid. Some have adjustable lengths, such as the FreedomWand, which may be useful for portability sake. The FreedomWand can also hold a shaver, ointment applicator, and bathing loofah.

Fig. 7.28 Schwabcare Wellness System utilizes an automated cleanser application, on-demand water heating system for gentle washing via programmable spray-head, advanced dryer and optional programmable hands-free bottom-up barrier spray applicator. A series of single-touch activation buttons located at the front of the seat allows the user to choose from a wash-and-dry only, initial cleanser or complete cycle with cleanse, wash, dry and barrier spray application

Advanced, water-based toileting systems allow for perineal washing, rinsing and drying (see Fig. 7.28). These systems allow for improved perineal cleansing via hands-free application of cleanser, followed by water lavage, efficient drying and hands-free application of various sprays as needed.

Urine collection devices using a vacuum are an evolving technology that is evolving. One such device, shown in Fig. 7.29, is a soft, flexible, external catheter wick that connects to a wall vacuum system or an optional dry dock vacuum station. The wick is designed to capture up to 100% of urine, regardless of flow rate. The wick does not attach or enter the body, but lies in between the labia in women and against the urethra. It is discarded after 12 hours of use. The device may be a helpful temporary collection system in women in an acute care setting and in those who are immobile.

Evidence-Base for Clinical Use

Toilet aids help to preserve the dignity and independence of a disabled person and may be crucial in enabling him or her to continue living at home. The most common difficulties experienced by the disabled are getting to the bathroom and sitting down or rising from the toilet seat. The various types of commodes, toilet frames, rails and urinals can help overcome these problems [69].

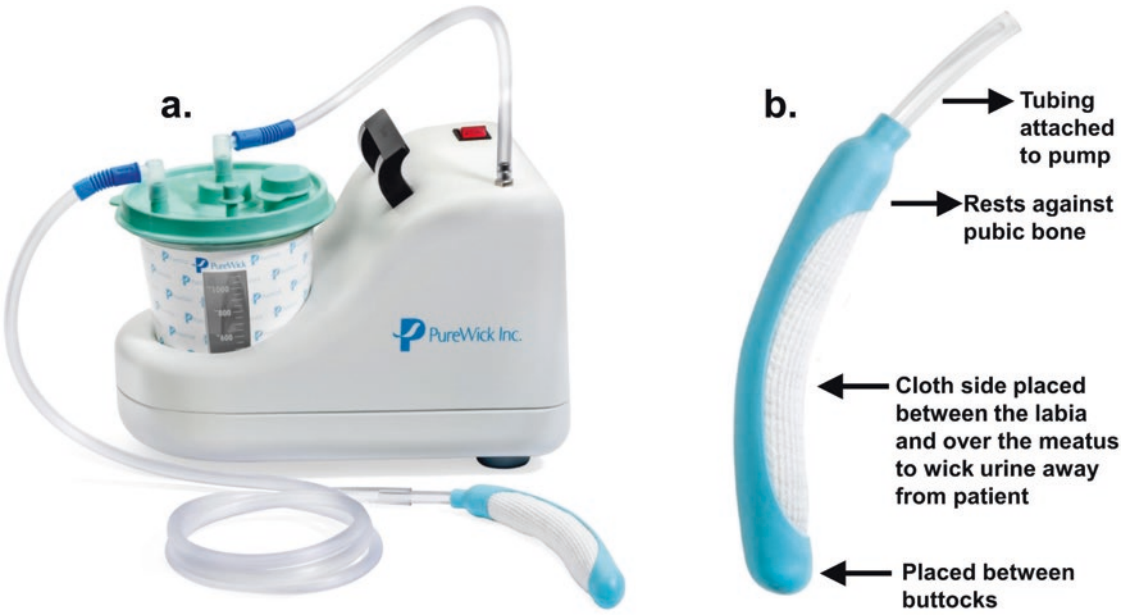

Fig. 7.29 External female collection device for women with UI—Courtesy of PureWick Corporation

Patient Information

- *How To Use a Penile Clamp Patient Education Tool*
- *Putting on the Finess™ Barrier Device Patient Education Tool*

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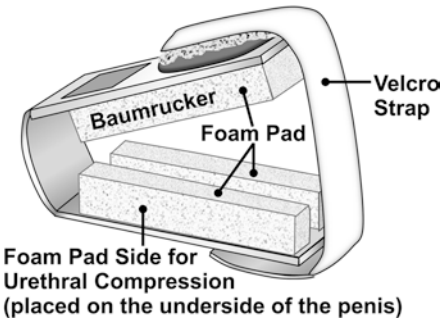
How to Use A Penis Clamp Patient Education Tool

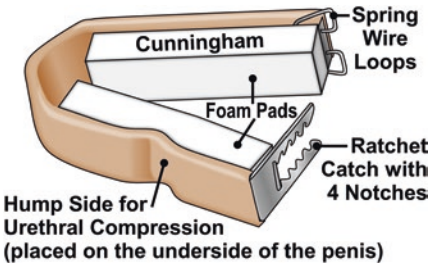
What Is a Penis Clamp?

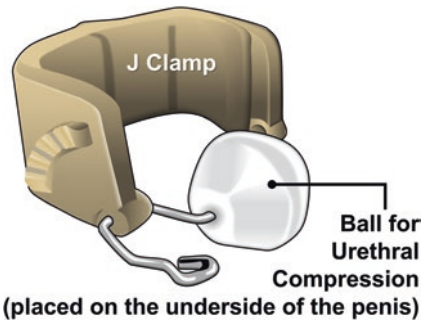
A penis clamp is a device used by men with urinary incontinence (unwanted leakage of urine) to stop urine leakage. It is also called a "penile compression clamp." It is placed around the penis and prevents urine leakage by putting pressure on the urethra on the underside of the penis. The clamp should only be used intermittently, only when you are awake and only for a few months, until replacement or resolution of urinary incontinence.

What Does a Clamp Look Like?

There are several kinds of clamps. Most clamps have flexible pads made of foam or silicone that are inside the clamp, against the penis. The pads can be shaped to fit your penis. The outside is made of metal or hard plastic. Here are pictures of a few types of clamps.

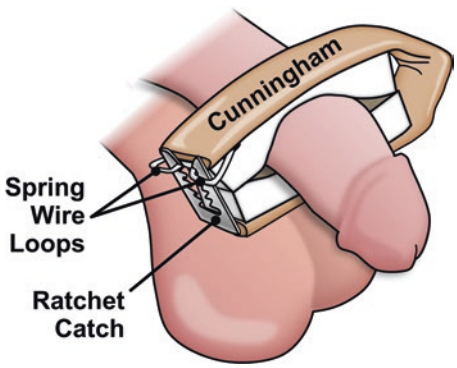






How Do I Put on a Clamp?

Open the clamp and place it around your penis, about halfway down the shaft. The hump side or ball of the clamp is placed on the underside of your penis. There are several ways to close the clamp depending on the kind of clamp you are using. Some have metal notches on the side to adjust the tightness, while others have a strap that is wrapped around the penis to compress the urethra. Compress the clamp using the method specific to that clamp (e.g., closed with a Velcro™ strap, insert catch through spring wire loops, or compression with use of a ball). To remove: release the mechanism that is compressing the clamp. It should spring open. If it has a Velcro™ strap, simply take off the strap.



TRY NOT TO USE THE CLAMP CONTINUOUSLY ALL DAY

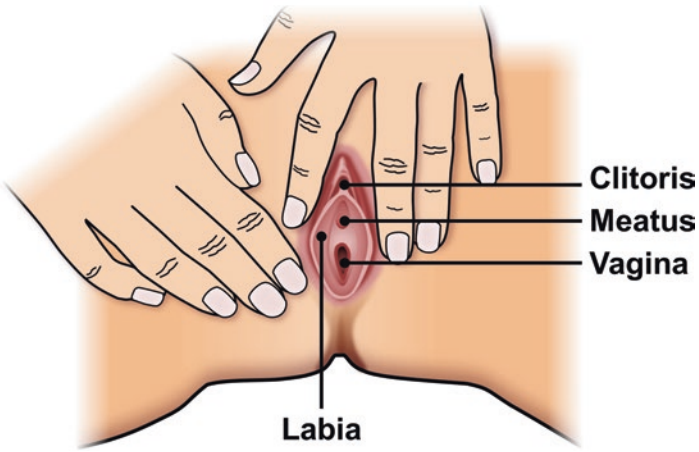
> ***You must release the clamp every 2 to 3 hours to urinate, whether you feel you have to or not.***

- If you do not release the clamp every 2–3 hours or more often, you may develop a bladder infection.
- Do not use the clamp at night when asleep.
- Do not compress or squeeze any clamp so tight that it stops blood circulation in your penis.

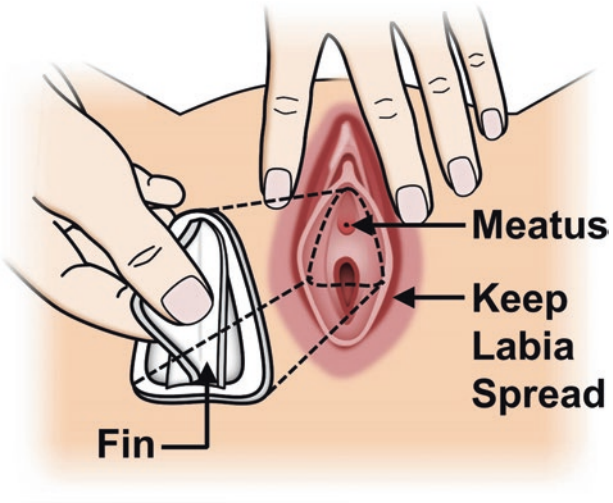
- When you take off the clamp, look at your penis for any skin openings. Stop using the clamp if you develop a skin reaction or irritation, pain, swelling, open sores, or signs of poor circulation.
- Most clamps can be washed with mild soap and water. Do not use bleach or any other detergent. Those that have foam pads need to be air dried after washing and before being reused.

Putting on the Finess™ Barrier Device Patient Education Tool

- The best position to put on the Finess™ Barrier Product is sitting on the toilet with legs spread.
- Open the package, take out the "fin" and peel off the cover on the adhesive side.
- If this is the first time applying the barrier device, use a hand mirror to locate the meatus. With your non-dominant hand (the one you do not write with) separate the labia and identify the meatus (opening to the urethra). It is found below the clitoris and above the opening to your vagina.



- Hold the device by the fin with the narrow (pointy) tip pointed up and the wider side towards the opening to your vagina. You may find it helpful to place a fingertip at the opening of the vagina and place the device in front of the finger.
- While keeping the inner and outer folds of the labia spread, place the flat adhesive side of the barrier directly over the meatus.
- Once in place, use a mirror to make sure the device is in the correct position. If positioned correctly, apply pressure over the center of the device so as to create a seal over the opening of the meatus.



- Remove the device when you need to urinate by gently peeling it off the meatus. Discard a used device as these are one-time disposable devices. The device should only be used for a few hours, not continuously.
- The device should be removed during sexual activity and when showering, as water will loosen the adhesive seal.

Perineal Skin Care Considerations

8

Kathleen E. Corcoran, Patricia Webster, and Jo Catanzaro

Overview

The focus of this chapter is on the specific strategies for maintaining optimal skin function for in individuals utilizing urologic catheters, products, and devices through informed use of available skin care products. The vast array of these products range in both purpose and function, as well as by ingredients and properties.

Properties and Function of Skin

The skin (see Fig. 8.1) is the largest organ of the body and its cells continually shed. It is often referred to as the "mirror of the body." The skin covers 3000 square inches of surface area, accounts for about 15% of body weight, and weighs 6 to 12 pound (lbs). It receives one-third of the body's circulating blood volume. The skin is acidic (pH 5.5 with a range from 4 to 6.8) and its thickness, texture, color and appearance vary. The skin's primary function is to provide a protective barrier.

In addition to establishing individual uniqueness, the skin serves several key functions in protecting the body from injury and disease. These include maintenance of body temperature, protection from the environment, and synthesis of vitamin D. The sensatory function of the skin affords further protection. The skin consists of three layers: epidermis, dermis, and subcutaneous (see Fig. 8.2):

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- *Epidermis*: the outermost layer of the skin is responsible for the biomechanical barrier function of the skin. The top layer of the epidermis, known as the stratum corneum (SC), is composed of layers that are continuously renewed and contains between 15 and 20 layers of flattened skin cells called corneocytes. Corneocytes comprise keratinocytes, cells filled with a tough fibrous, insoluble protein, known as keratin, which is resistant to change in temperature and pH [1]. Excessive skin surface moisture can cause overhydration of the keratinocytes and disruptions of the intercellular lipid bilayers. As a result, the corneocytes swell and the thickness of the SC increases leading to breakdown. Increased skin pH will lead to more swelling of the SC, causing the skin to be more permeable and compromising the skin barrier function. In addition to appropriate pH, SC function depends on water. The primary water source of the SC lies deep down in the subcutaneous tissue and it has to move to the surface to hydrate the upper layers. SC architecture is key to this water migration. The structure of both the corneocytes and the lipid layers of the SC combine to both move and maintain moisture that contributes to the skin's physical barrier property and elasticity [2]. The lipid layers provide a moisture barrier but also function to regulate the entry of topical skin products into the SC when applied externally. Inside the corneocytes, the lipid substance, the Natural Moisturizing Factor (NMF) also helps to regulate SC hydration. NMF, made up of amino acids and salts, is produced in direct relationship to external humidity. Finally, maintenance of the SC architecture requires normal turnover of cells by desquamation. Desquamation is orchestrated by enzymes and is water dependent. Corneocytes over-accumulate on the skin when the water content is less than 10% or when skin continuity is breached [3].
- *Dermis*: lies directly beneath the epidermis, is the second layer of skin and contains both blood vessels and nerve endings as well as proteins like collagen and elastin. The latter provide support and elasticity. This layer also contains macrophages and lymphocytes, cells important in the protection from invading organisms.

D.K. Newman et al., *Clinical Application of Urologic Catheters, Devices and Products*, DOI 10.1007/978-3-319-14821-2_8

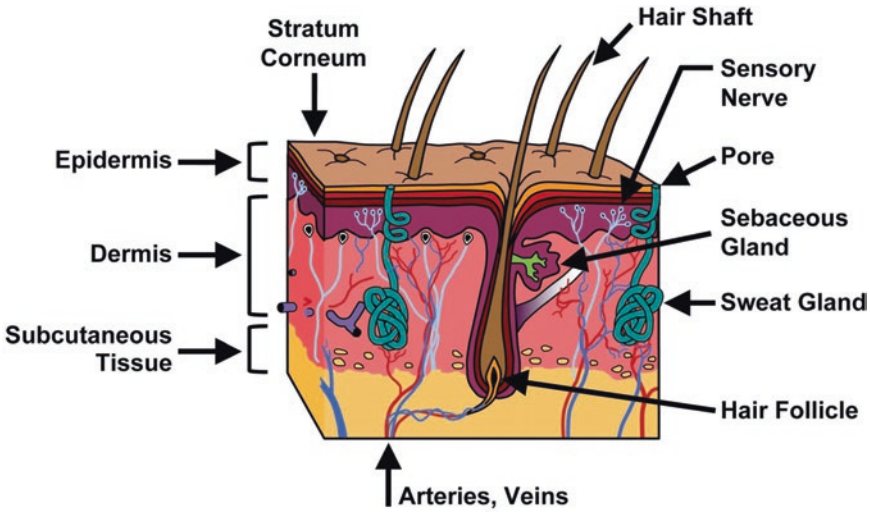


Fig. 8.1 Cross section of the skin

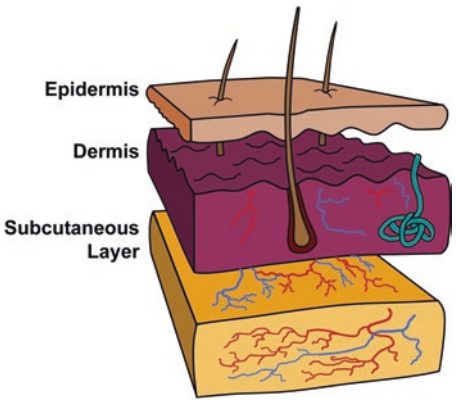


Fig. 8.2 Layers of the skin

- *Subcutaneous* (SubQ) or *hypodermis*: lies under the epidermis and dermis. It is several millimeters thick and is composed primarily of connective tissue, blood vessels, and fat. It attaches the dermis to underlying structures and promotes an ongoing blood supply to the dermis for regeneration. The hypodermis is primarily adipose (fat) tissue that provides a cushion between skin layers, muscles and bones. It stores fat for energy, provides insulation for temperature control, and aids in protection through its soft cushioning effect.

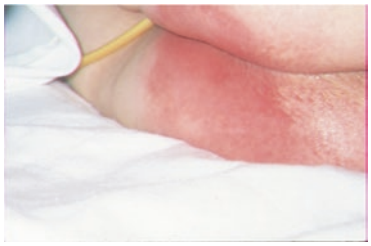
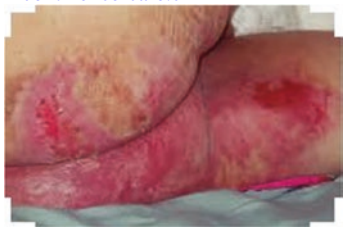
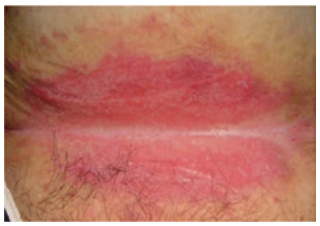
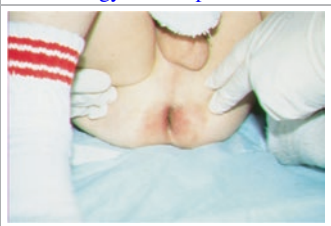
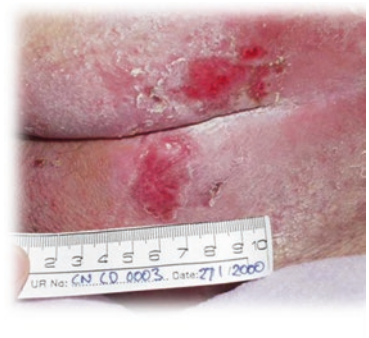
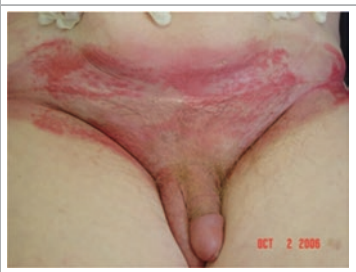
Definitions

Incontinence exposes the skin to moisture, digestive enzymes, microorganisms, and alkalinizes skin pH; these conditions are thought to alter skin integrity and precipitate dermatitis. Individuals with severe intractable urinary incontinence (UI) and/or fecal incontinence (FI) are often immobile and at major risk for skin breakdown. Historically, a variety of terms have been utilized to describe skin conditions in the perineal area including: diaper rash, perineal dermatitis, perianal rash, contact dermatitis, irritant dermatitis, moisture maceration injury and heat rash [4, 5]. The universal term currently used for skin damage resulting from exposure to stool and/or urine is incontinence associated dermatitis (IAD) [1, 6]. IAD is defined as a skin inflammation, manifested as redness with or without blistering, erosion, or loss of the skin barrier function that occurs when urine or stool comes into contact with perineal or perigenital skin. IAD describes the primary clinical manifestation caused by exposure of the skin to urine and stool (inflammation), and identifies the source of the inflammation as UI and/or FI [1, 7]. Moisture must be present and the erythema is superficial (partial thickness skin loss). According to a 2015 Cochrane Collaboration review [4, 5], IAD is sometimes accompanied by bullae with serous exudates or secondary cutaneous infection. IAD can range in severity from erythema with or without loss of skin integrity to infection. Erosion or denudation of superficial layers is generally associated with more advanced or severe cases [1].

The current version of the ICD-10 contains codes for "diaper dermatitis" (skin damage in infants and toddlers prior to toilet training), but not IAD [8]. A diagnostic code is needed to describe this skin condition in adults. IAD is costly, painful and, for the most part, preventable [9].

IAD is considered part of a broader group of skin conditions that are referred to as "moisture-associated skin damage" (MASD) [4, 5]. MASD is considered an umbrella term that describes the spectrum of damage that can occur as a result of the prolonged exposure of a patient's skin to various sources of moisture (urine or stool, perspiration, wound exudate, mucus, or saliva) [6, 10]. But, IAD is the preferred term as it identifies the problem directly with the UI and/or FI and not with other conditions (such as perspiration or wound exudate) [8]. In addition to IAD, other skin conditions are also seen which include erythema, maceration, intertrigo and pruritus ani, as well as secondary bacterial, and/or fungal infections (see Table 8.1).

Table 8.1 Common incontinence-associated skin conditions

Skin problem	Picture	Definition	Appearance, signs, symptoms
Erythema		• Inflammatory response of the skin caused by dilation and congestion of the capillaries	• Presents as a red, macular rash that may be sensitive and tight • Edema may be present • May have increased skin temperature from the inflammation
Maceration	http://www.sageproducts.ca/products/incontinence-care/all-in-one-incontinence-care.cfm 	• Superficial erosion of the skin from overhydration due to prolonged exposure to moisture (e.g., urine, liquid stool) • Areas include perineal skin, abdominal and breast folds, tube sites, between toes and fingers, and skin surrounding wound sites	• White appearance of the skin with a very soft, sometimes "soggy" texture • Moisture barriers and/or absorbent dressings should be used on all areas at risk for maceration and on maceration that occurs around wound edges
Intertrigo	 http://www.edoctoronline.com/dermatology-atlas.asp?c=4&id=24875	• Partial-thickness skin loss that occurs on opposing skin surfaces as a result of perspiration, friction, and maceration • Inflammatory condition of skin folds, induced or aggravated by heat, moisture, maceration, friction and lack of air circulation • At-risk patients includes those who are obese, have impaired mobility or have diabetes	• Erythema, superficial line erosions at base of gluteal fold and circular erosions between buttocks
Pruritus ani		• Inflammation of the peri-anal area directly related to perineal hygiene that includes overzealous wiping or cleansing of the anal area • Can also occur as a generalized pruritus in patients with systemic diseases such as liver or renal failure	• Bouts of intense peri-anal itching and chronic scratching causing linear lesions • Often misdiagnosed as IAD
Secondary skin infections			
Bacterial		• Caused by numerous microorganisms, particularly the bacteria *Staphylococcus epidermidis* • Occurs when balance between the host and microorganisms is altered	• Occur following a break in the skin, as a secondary infection to already damaged skin or as a sign of a systemic disease • These infections irritate and inflame the skin, decreasing its ability to be an effective barrier • If FI exists, may develop bacterial infections from Gram negative organisms
Candida albicans or Candidiasis (fungi, yeast)		• Most common opportunistic skin infection that results from a warm, moist environment (e.g., perineum, groin and thigh folds) • Penetrates the compromised epidermis and damages SC • More often seen in those who are obese, have diabetes, are on long-term antibiotic therapy, and/or have AIDS	• Characterized by a bright to dull red central area with peripheral red pustules that can develop into secondary lesions of papules if damaged by friction or shearing • Skin is usually very erythematous and pruritic and may be tender and very itchy • In darkened skin, the central area may appear as darkened skin. It has an erythematous base that may itch or burn • Spread of the lesions is inhibited when it reaches dry skin

According to the National Pressure Injury Advisory Panel [11], a pressure injury is defined as "localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities, and condition of the soft tissue" [11]. Consequently, the location of the impaired integrity and distribution of the breakdown are important considerations in determining diagnosis and developing a subsequent treatment plan.

Differentiating IAD from pressure related partial-thickness skin loss can be particularly challenging for clinicians (see Table 8.2). Despite differences between IAD and pressure injury in both location and presentation, in many cases, patients in many cases may present with lesions of mixed etiology due to shared risk factors. The aging process itself predisposes the skin to an increased risk of both injury and infection.

Table 8.2 Differentiation between pressure injury and incontinence associated dermatitis

Assessment	Pressure injury	IAD
Location	Typically bony prominences	Absorbent product areas Extreme cases may extend beyond containment product
Tissue involvement	Partial to full thickness	Partial thickness
Appearance	Varies from erythemic or ischemic epidermis to necrosis of deeper tissue layers and supportive structures	Diffuse borders Moist, shiny, taut, epidermis to shallow erosion(s) with exposed dermis
Prevention	Offloading and protection from shear forces	Skin care regimen focusing on cleansing, moisturizing and protection from external irritants
Complications	Necrosis of tissue and supportive structures, secondary infection, loss of function	Secondary bacterial/fungal infection Predisposition to pressure injury
Risk factors	Immobility Incontinence Co-morbidity Impaired nutrition Impaired cognition Impaired sensory function	Immobility Incontinence Co-morbidity Impaired nutrition Impaired cognition GU/GI system factors Previous surgery Hormonal changes

Etiology of Incontinence Associated Dermatitis

The relationship between incontinence and perineal skin breakdown comes from the presence of excessively moist or wet skin and the breakdown of the normal, healthy integrity of the skin. IAD is a "top-down" injury where the epridermis suffers superficial damage. The dermal injury caused by excessive moisture (see Fig. 8.3) itself is not entirely understood, but is believed to involve a complex cascade of events that can act upon one another in a self-perpetuating cycle as depicted in Fig. 8.4. Potential sources include UI and/or FI, liquid stool, frequent washes, poorly ventilated containment or a bodyworn occlusive product (e.g., external catheter, absorbent product or bed pad, penile clamp), and skin occlusion. Continued exposure to potential sources is a direct factor in skin breakdown, and the median time to onset of IAD can range from 4 to 13 days after this exposure. Other risk factors for IAD include poor skin condition, secondary to diabetes, etc., compromised mobility, pain, cognitive impairment, poor nutritional status, inability to perform personal hygiene, and critical medical status [4, 5].

Urea in urine is decomposed by bacteria to ammonia, a highly irritating substance. The perineal skin does not tolerate being wet for long periods of time, and the wetness destroys the natural barriers for the skin's protection against destructive agents such as urine.

Normally, the SC, sebaceous gland secretions and the skin's immune system furnish protection against aqueous, chemical, bacterial, and viral pathogens [1]. In addition to keratin in the SC, sebum, an oily substance secreted by the sebaceous glands, provides both moisturizing and water resistance protection to the skin. Sebum also maintains the natural mildly acidic pH of skin from 4 to 6 which retards the growth of microorganisms [9]. As discussed, IAD can range

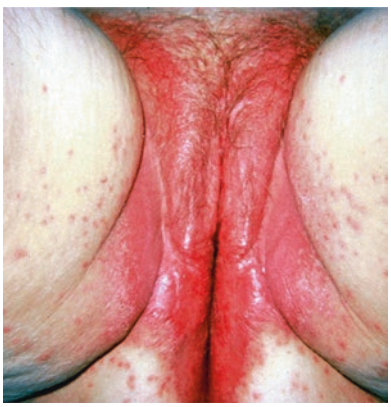


Fig. 8.3 Dermal injury caused by moisture

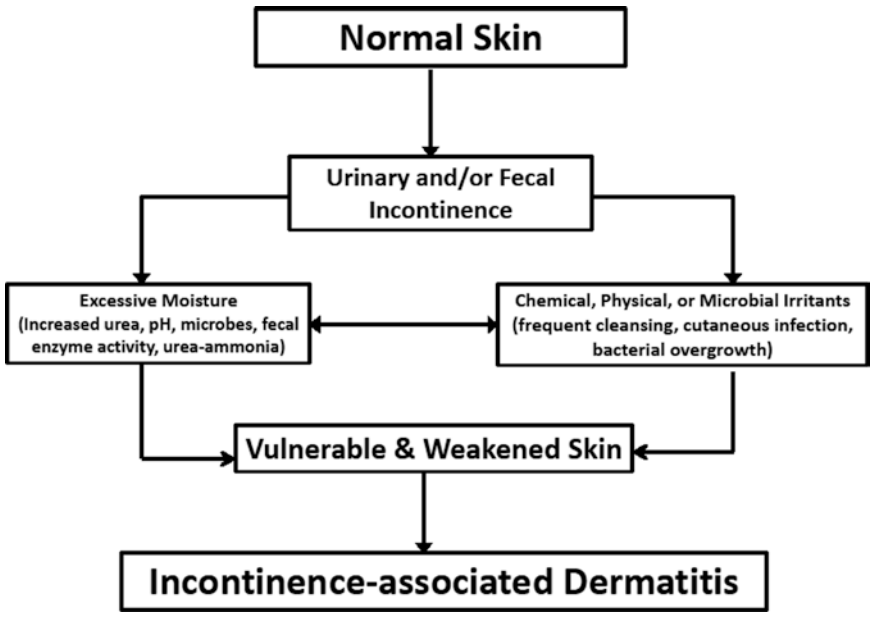


Fig. 8.4 Cycle of dermal injury [12]

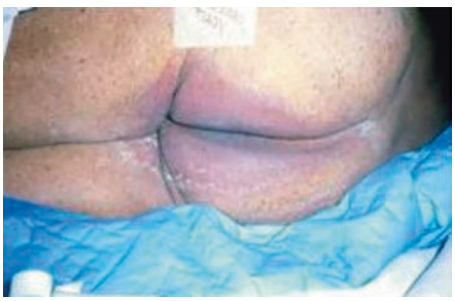


Fig. 8.5 Mild IAD Wound, Ostomy and Continence Nurses Society (2007). *The WOCN image library [Image database]*. Retrieved from http://images.wocn.org. In-text citation: (*Mild Irritant Dermatitis*; Wound, Ostomy and Continence Nurses Society 2007)

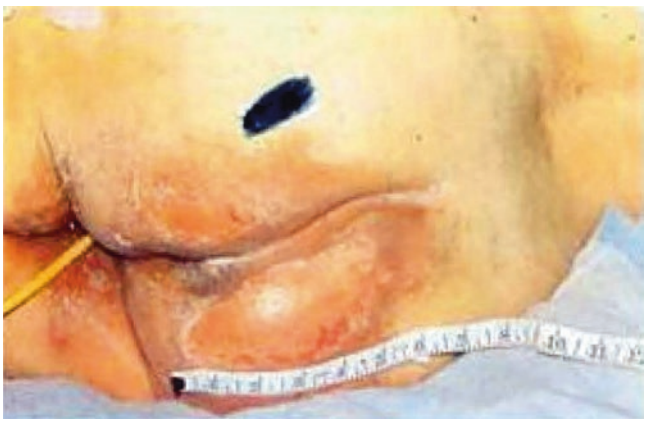


Fig. 8.6 Severe IAD Wound, Ostomy and Continence Nurses Society (2007). *The WOCN image library [Image database]*. Retrieved from http://images.wocn.org. In-text citation: (*Severe Irritant Dermatitis*; Wound, Ostomy and Continence Nurses Society 2007)

from mild inflammatory changes in the skin to infection. Figures 8.5 and 8.6 depict mild to severe IAD. Frequent and prolonged contact with moisture can precipitate inflammation by facilitating the passage of irritants into the skin, leading to dermatitis [13]. Urinary and/or fecal incontinence can be detrimental to the delicate pH balance. The natural acidic pH of the skin ranges between 4 and 6.8 with a mean of 5.5. The skin pH range is referred to as the "protective acid mantle." Perspiration can increase the pH from 7.0 to 7.5, while urine and feces can increase pH to 8 or greater. Ammonia is alkaline and, therefore, raises the pH of the skin when it is in prolonged contact with urine or feces. If the skin becomes more alkaline, its ability to inhibit bacterial growth is compromised [14]. Fecal incontinence can cause dermal and epidermal erosion (see Fig. 8.7). Numerous integumentary changes occur over time, including diminished elasticity, decreased in the number and function of sweat glands, and a reduced collagen.

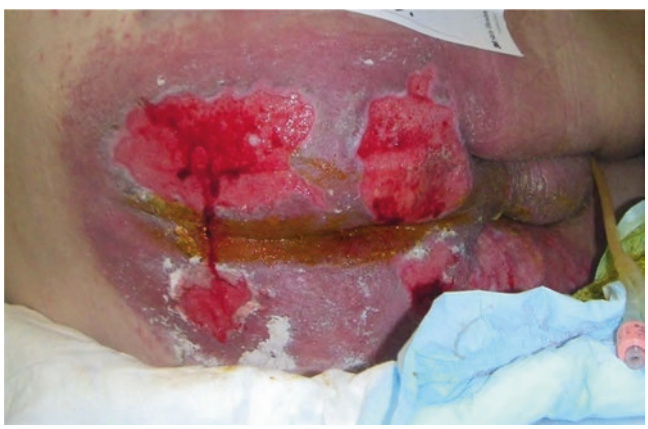


Fig. 8.7 Dermal and epidermal erosion secondary to fecal incontinence Wound, Ostomy and Continence Nurses Society (2007). *The WOCN image library [Image database]*. Retrieved from http://images.wocn.org. In-text citation: (*Buttocks skin breakdown*; Wound, Ostomy and Continence Nurses Society 2007)

Prevalence

Prevalence of IAD in hospitalized patients is 27% [1] and 43% for residents in skilled nursing facilities [1]. Incidence varies with population and care setting, ranging from 3.4 to 25% [1]. However, research regarding the prevalence of IAD and related moisture associated skin impairment has been wrought with the challenges from under-reporting, particularly due to embarrassment and stigma associated with UI and/or FI. Also, general perception and lack of understanding of the differences between IAD and pressure injury identification creates an additional are further hindrances.

Predisposing factors for IAD are also risk factors for development of a pressure injury. A 2012 multi-center investigation of 3,713 incontinent patients (mean age 81.2) in hospitals, nursing homes, and home care in Austria and the Netherlands reported an IAD prevalence of 6.1% and demonstrated there is a higher incidence of IAD in persons who have FI, moist perineal skin, higher BMIs, diabetes, and who need increased assistance in moving [15].

The development of IAD can have a considerable effect on patients physical and psychological well-being [12]. It can result in an "undue burden of care, loss of independence, disruption in activities, sleep, and reduced quality of life, worsening with frequency and quantity of soiling" ([8], p. 2).

Although IAD and pressure injuries may co-exist, especially in individuals who are both immobile and suffering from UI and FI, each of these conditions have distinct characteristics. Careful examination is crucial to making a precise diagnosis so that an individualized plan of care can be established.

Assessment

Symptoms of IAD include discomfort, pain, burning, itching, and/or tingling in the affected areas. Examination should include both inspection and palpation, and should be conducted frequently (e.g., every 8 hours (h)) on all patients with either UI and/or FI. Inspect perineal skin for excessive moisture, excoriation, and erythema or irritation. IAD presentation can range from erythema (with or without loss of skin) to cutaneous infection (such as candidiasis) [16]. In persons with light skin, erythema can be pink to red in color. Lesions may present as vesicles or bullae, papules, or pustules. The epidermis may or may not be intact. In cases where secondary infection is present, the appearance may include satellite pinpoint lesions, vesicles or erosion. Fecal incontinence, especially in high volumes, can be especially destructive and can result in erosion of the epidermis and dermis due to the presence of digestive enzymes (Table 8.2). The skin in the affected area may be warm. Inspection should be performed when removing clothing, protective pads, dressings, and/or containment devices.

Assessment of the perineal skin includes inspection of the sacrococcygeal, the gluteal cleft, the perianal, the buttocks, upper thighs, external genitalia and suprapubic areas (see Table 8.3). The skin will appear shiny and taut with redness and tenderness with diffuse borders, but limited to exposed areas (typically the buttocks, perineal, peri-genital, and peri-anal areas and skin folds of the groin, and upper thighs).

In men with UI who are using an external male catheter, IAD will start at the glans (tip) of the penis or foreskin if uncircumcised and spread down the penile shaft. In both men and women, assessing for IAD requires regular inspection of areas at risk for breakdown, particularly in cases where disposable incontinence absorbent products are being utilized [18]. If a man is using an incontinence absorbent product, IAD will usually be seen in the inner folds of the scrotum. Often products designed specifically for incontinence create an occlusive environment and persistent exposure of the skin to wetness that pervades the naturally protective epidermis.

Chronic insult of the skin by moisture, including elements of urine and feces results in an inflammatory response. Extreme cases may include extension of skin damage to the sacrum, upper back, upper thighs, and abdomen.

Evidence-Based Research for IAD Prevention

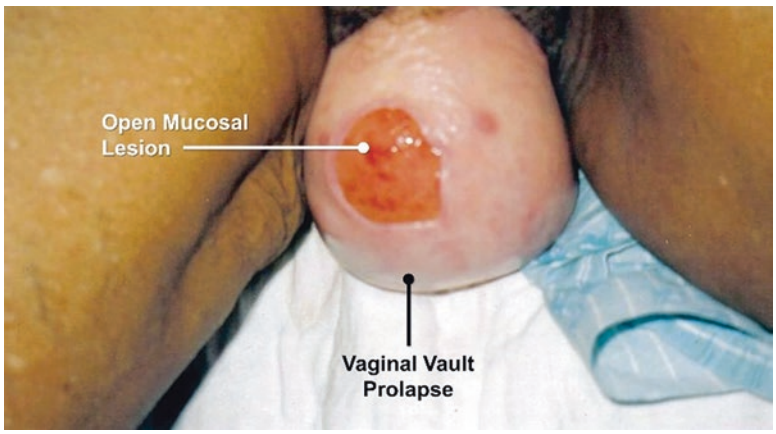
There are several consensus statements that review the evidence-base for IAD. The 2011 Wound Ostomy Continence Nurses (WOCN) Society Continence Committee published a *Best Practice Document (BPD) for Clinicians on Incontinence Associated Dermatitis* (www.wocn.org, [19]) that summarizes the current data on IAD, establishes definitions, and reviews the literature on prevention and treatment strategies. In 2014, the Global IAD Expert Panel published *Best Practice Principles Incontinence Associated Dermatitis: Moving Prevention Forward* [4, 5], a comprehensive literature review of the current evidence base for IAD epidemiology, assessment, prevention, and treatment. Both documents note that primary IAD management starts with prevention by managing the incontinence and minimizing skin contact and exposure to irritants present in urine and feces. This important first step promotes the maintenance of the skin's functional capacity to protect itself, reducing pain and the potential for secondary cutaneous infection and damage.

A basic understanding of a product's functional characteristics and ingredient profile is fundamental to appropriate selection and use. Products can be categorized into three major groups: cleansers, skin protectants, and moisturizers. Ingredients may vary in each category. Table 8.4 provides a classification of skin care product ingredients. Doughty et al. [19] summarize the literature on the effectiveness of various prevention and treatment strategies classified according to strength of evidence. Pather et al. [20] performed a system-

Table 8.3 Perineal skin examination

External perineal skin—women

- Assess for rash, skin lesions, odor, and discharge
- Separate the labia and visualize the urinary meatus, note any redness, inflammation, erythema ulceration, urethral or vaginal discharge, swelling, or nodules. Excoriations and maceration of the vulva may occur with constant wetness or may be secondary to infection
- Expose the skin folds between the mons pubis, vulvar:
  - External genitalia (labia majora and labia minora) should be examined for dermatologic lesions and evidence of irritative or inflammatory conditions, such as rash or skin lesions. Labial skin may be slightly darker than surrounding tissue, and, in older adult women, may be pale
  - Excoriation and maceration of the vulva may occur with constant wetness or may be secondary to infection. The internal vulva should be examined for estrogen deficiency (atrophy) which appears as a red, dry membrane instead of moist, pink tissue
  - Note if there is a protrusion from the vagina indicating possible pelvic organ prolapse (uterine or bladder). If a prolapse extrudes outside of the body, it may become dry and lesions will occur



- Check skin folds, the inner aspect of the upper thigh and inguinal folds. They are often overlooked during perineal bathing and are a frequent site for bacterial and fungal growth
- Separate buttocks and inspect coccyx and anus

External perineal skin—men

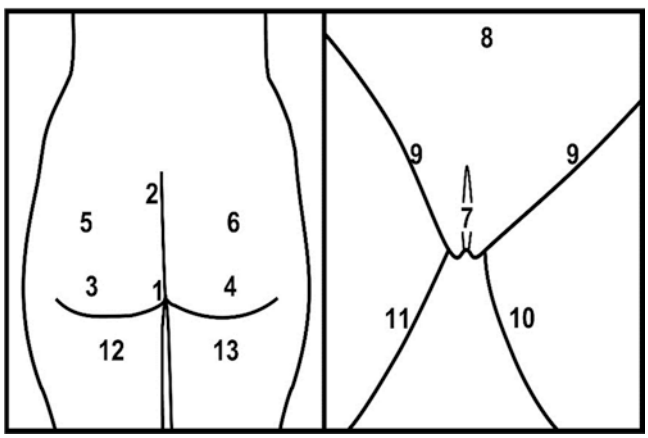
- Assess all parts of the penis, the glans (tip) and penile shaft, noting any redness or rash
  - In uncircumcised men, retract the foreskin, inspect the glans and meatus. Retracting the foreskin is a very important component of personal hygiene in uncircumcised men. A cheesy, whitish material called smegma may accumulate normally under the foreskin. Replace foreskin back over the glans.

- Scrotal skin is usually darker than adjacent perineal skin, and may be slightly reddened if the person has red hair
- Observe the perineum, the area behind the scrotal sac to the anus
- The inguinal folds should be gently separated and assessed because this is a common area for increased perspiration leading to the development of secondary infections, such as *Candida albicans*
- Assess skin over the coccyx and buttocks. Separate buttocks and inspect anus

If IAD is observed, the use of an instrument [17] will assist in identifying the severity by noting the specific location:

Locations:

1. Perineal skin
2. Crease between buttocks
3. Left lower buttocks
4. Right lower buttocks
5. Left upper buttock
6. Right upper buttock
7. Genitalia (labia/scrotum)
8. Lower abdomen/suprapubic
9. Crease between genitalia and thigh
10. Left inner thigh
11. Right inner thigh
12. Left posterior thigh
13. Right posterior thigh



Redness:

☐ None ☐ Pink ☐ Red ☐ Bright red

Skin Loss (Skin is moist as top layer is missing):

☐ Yes ☐ No

Rash (An area of redness with an irregular edge and pinpoint red dots trailing off from edge):

☐ Yes ☐ No

Borchert K, Bliss DZ, Savik K, Radosevich DM. The incontinence-associated dermatitis and its severity instrument: development and validation. J Wound Ostomy Continence Nurs. 2010 Sep.-Oct;37(5):527–35. doi: 10.1097/WON.0b013e3181edac3e

atic review of topical skin products in the prevention and treatment of IAD. Only clinical studies were considered. Despite the prevalence of IAD, a total of only 804 participants were included across all 10 studies. One of the findings was that use of a skin protectant product was beneficial in preventing and treating IAD.

Skin care practices for those urologic patients with UI and/or FI include prevention and management of IAD. Clinicians should choose a product or type of products that mimic the skin barrier's function, with a pH close to that of intact healthy skin and that remains on the skin as a waterproof protectant. The following is a review of product categories that should be considered in these patients.

Table 8.4 Classification of IAD product ingredients

Product function	Ingredient	Action
Barrier	• petrolatum • Olive oil • Coconut oil • Waxes • Silicones	• physical barrier to TEWL • may cause folliculitis
Humectants	• glycerine • Glycerol • Sorbitol • Urea	• water binding, pulls from subcutaneous tissue • may cause dryness • may have emollient property
Emollient	• lanolin • Paraffin • Ceramides • Silicone • Mineral oil • Castor oil	• fills in skin surface irregularities • some may have humectants property

Cleansers

Available perineal skin cleansing products range from soap and water to specialized combination formulas that afford one step, pH balanced, no rinse cleansing and protection (see Fig. 8.8). Multiple studies compare various regimens for both cost and effectiveness. Gray [1] describes how soap functions to remove dirt by breaking down to free alkali and acid salts. These substances have a higher pH than healthy skin, are not physiologic and may not be appropriate in patients with UI and/or FI. In contrast, perineal skin cleansers for incontinence combine detergents and surfactants to remove irritants, and have a more physiologic pH profile that maintains the skin's acid mantle protection. Consequently, the aforementioned consensus on best practices for prevention of IAD recommends the use of a perineal skin cleanser over soap and water. There are also continence care wipes that are made of smooth material that reduce friction when used (see Fig. 8.9). Beeckman et al. [21] note that wipes have been found to enhance staff adherence to skin protocols, reduce burden of care, and improve staff satisfaction. Many wipes contain a cleanser, skin protectant, and moisturizer (referred to as 3-in-1).

Skin Protectants/Barrier

This product category is designed to provide a barrier for the skin against both the irritants present in urine and feces and, the damaging effects of excess moisture. Examples of simple barrier ingredients include petrolatum, dimethicone, zinc oxide, lanolin, and co-polymer film. Combination products are also common in this category, offering skin protection

Fig. 8.8 (**a**) Perineal cleanser (All-in-One perineal cleanser)—(Baza Cleanse & Protect®)—Courtesy of Coloplast Corp. (**b**) 3-in-1 cleansing cream (Tena®)—Courtesy of Essity (formerely SCA Hygiene Products)

Fig. 8.9 Continence care washcloths—(Attends®)—Courtesy of Domtar Personal Care

Fig. 8.10 (**a**) Clear moisture barrier ointment (Citric-Aid® Clear)—Courtesy of Coloplast Corp; (**b**) clear moisture barrier ointment with antifungal (Citric-Aid® Clear AF)—Courtesy of Coloplast Corp.

and moisturizers in one product (referred to as moisture barriers) (see Fig. 8.10a). Various antimicrobials may also be added. Again, the clinician should understand the product function and ingredient profile to make appropriate treatment selection and address the specific needs of the clinical situation. Protectant products are made with a base agent that provides a barrier for the skin. Some products will add a moisturizer for dry skin and an "active ingredient" for a specific purpose; for example, an anti-fungal or a skin healing agent (see Fig. 8.10b). Finally, the carrier formula (paste, ointment, or cream) should be considered. Thick occlusive skin protectant products may limit fluid uptake of absorbent incontinence products [22]. These characteristics will inform both application and removal. They also influence the degree of skin occlusion by the product and the effectiveness of absorbent products in use. Patient evaluation is necessary to guide product selection for individual needs (http://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf).

Fig. 8.11 Moisturizing body cream (Sween® cream)—Courtesy of Coloplast Corp.

Moisturizers

In contrast to barrier products that function to protect skin from excess moisture, the goal and function of this product category is to donate moisture to dry, fragile skin (see Fig. 8.11). This moisture donation can be achieved by product formulations, defined as emollients or humectants that draw water from deeper tissue into the skin. An additional function to maintain the skin moisture barrier function is by the control of transepidermal water loss (TEWL). The effectiveness of these actions will vary with the product ingredients, as well as by the products vehicle formula and, the amount of water in the formula. Liquid moisturizers, for example, have a higher percentage of water than creams, and thus more liquid the product. These products may evaporate faster off the skin and be less effective in controlling TEWL [19, 23].

Prevention

Multiple factors place urologic patients at higher risk of IAD. Fecal incontinence has been found to be most strongly associated with IAD [24]. Skin exposure to urine

alone or with soft, formed stool is associated with low risk. Risk of skin damage rises when stool is loose or liquid, and when combined with urine [9].

Prevention of IAD should begin with diagnostics for the cause of UI or FI along with a treatment plan for the diagnosed pathology. The use of urologic catheters, products or devices are reviewed in other chapters; if UI is present with their use, prevention measures for IAD are mandated. The WOCN Society's Best Practice Guidelines suggest, a "structured regimen" for skin care. Such a protocol should combine the use of a skin cleanser, moisturizer, and protectant (see Table 8.5). For adequate prevention of IAD, staff education on the appropriate use of these products and implementation of the protocol is vital. Additionally, since this form of skin damage is caused by UI and/or FI, correcting reversible causes is the only intervention that is guaranteed to eliminate its occurrence [7].

Management – Skin Care Program

A review of current literature reveals that two main principles provide the basis for prevention and management of IAD - avoidance of contact between urine/stool and the skin, and implementation of a skin care regime which repairs and restores skin integrity and protects the skin from further damaging effects of urine and feces [25]. The skin care regime should consist of gentle perineal cleansing, application of a moisturizer if appropriate and application of a skin protectant or moisture barrier [7, 26]. Table 8.6 reviews components of perineal cleansing in females and males

Providing 'moisture' is more complex than it sounds, especially when excess moisture from various body fluids is the underlying cause of the problem. Moisturizers are commonly believed to decrease TEWL, but they must also function to restore the lipid barrier and support the ability of the SC to hold and re-distribute water. Characteristics of the 'ideal' moisturizer product include 1) effective hydration, 2) ability to make the skin smooth and supple, 3) ability to restore the lipid barrier enhancing natural skin moisture retention, 4) non-sensitizing and hypoallergenic quality, 5) affordablility, 6) long-lasting nature and 7) rapid absorption [3]. 'Moisturizer' products must moisturize with a specific pH and in a formulation that will not alter the structure and function of the SC architecture. Various product formulas may improve or further impair skin barrier function.

Topical application of a substance will follow a combination of three potential pathways, the substance may dissipate

Table 8.5 Prevention of IAD

Intervention	Rationale
• Assess perineal skin for redness (dermatitis), rash or skin breakdown • Determine presence of skin infections (especially fungal and staphylococcus)	• If UI and FI result in increased skin wetness (due to urine) and permeability (due to bowel enzymes), perineal skin breakdown can occur. Both urine and feces contain substances that may irritate the epidermis, making the skin more susceptible to breakdown • Constant moisture in the vulvar zone and perineum can lead to skin maceration and infection • Skin breakdown will appear as a localized area of erythema or skin discoloration, while IAD may appear as a more diffuse area of erythema or discoloration where the urine or stool has come into contact with the skin • Dermatitis may occur in an area where the absorbent product or underpad has been used
• Inspect skin daily in person who is using a collection device (e.g., external catheter or pouch)	• Catheters and devices can cause skin breakdown from moisture, friction, and shear
• Keep perineal area clean and dry with a perineal cleanser or disposable cloth or wipe at each change of incontinence product • Avoid repetitive, vigorous skin cleansing and the use of soap and water	• Aggressive skin cleansing, and drying of urine and feces (e.g., using cloth washcloths and towels) can increase frictional forces and cause breakdown of epidermal layer. When the skin is moistened, repeated washing with soap and water alters its protective acid mantle • Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown than moisture barriers and no-rinse cleansers • Many soaps and cleansers have an alkaline pH, which causes the pH of the skin to increase, making it more vulnerable to enzymatic and chemical irritants • Perineal cleansers are more pH balanced than soap and water
• Apply a moisturizer or protective skin barrier product to affected area, especially if skin is excoriated	• Moisturizers (creams, lotions or paste) help preserve the moisture in the skin by either sealing in existing moisture or adding moisture • Use sparingly—if at all—on already macerated or excessively moist skin • Skin barrier products repel irritants and moisture by providing a water-repellant coating to the skin
• Change incontinence product when saturated with urine or feces	• Persistent exposure of perineal skin to urine and/or feces from saturated absorbent products can irritate the epidermis and cause severe dermatitis or skin erosion. • Skin erosion is the loss of some or all of the epidermis (compared to a deep chemical peel) leaving a slightly depressed area of skin.
• Avoid prolonged sitting with any at-risk patient	• Sitting too long on a static surface can cause ischial ulceration. Reduced mobility and limited ability to move independently in bed and chairs causes friction and shear loads in the epidermis diminishing the strength of its barrier • Slouching in a chair may predispose an at-risk patient to pressure injury of the spine, scapula, or elbow (elbow ulceration is often related to arm rests or lap boards) • Friction and shearing are also important factors in tissue ischemia, necrosis, and pressure injury formation

(continued)

Table 8.5 (continued)

Intervention	Rationale
• Evaluate nutritional status with careful examination of eating habits and dental status	• Increase protein intake to stimulate collagen production. Severe protein deficiency causes soft tissue to breakdown when exposed to local pressure • Maintain adequate hydration • Consider Vitamins C and Zinc if hypoalbuminemia. Consider Vitamin A if patient is taking steroids and analgesics • Consult with nutritionist
• Prevent friction and shear	• Elevate head of bed no more than 30 °, as shearing can occur when the head of the bed is raised more than 30° • Consider the use of aids, such as lifts and sheets, when positioning or lifting, as opposed to "dragging" or sliding the patient on the bed or chair, which causes increased pressure, friction, and shearing

• Ensure proper positioning, function of, or ability to, distribute a load over a surface or contact area. Proper body redistribution is:
  • Repositioning bed-bound individuals at a minimum of every 2 h, chair-bound persons every hour
  • Start a 2 h repositioning time interval and then individualize the schedule
	• Redistribution results in shifting pressure from one area to another and requires attention to all affected areas
	• Clinicians should tailor a turning schedule to the individual patient's needs, as a traditional 2-h turning schedule may not be frequent enough
	• Use a posted turning schedule to help communicate when turning occurred

Table 8.6 Important points about cleansing the perineal area in patients with UI and/or FI

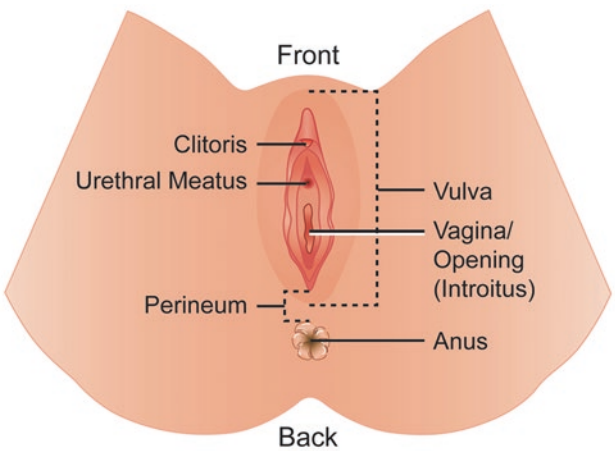
The perineal and peri-anal areas should be cleansed daily, after removal of an incontinence product and after every bowel movement, liquid stool or FI episode

Considerations:

- Soap and water applied with a washcloth, has traditionally been thought of as a gold standard for skin hygiene. Soap and water with a washcloth will cleanse the skin, but repeated use tends to dry the skin and most soap and cleansers have a high, alkaline pH
  - Soap removes the skin's natural lipids; it also decreases natural lubricants, which leads to increased TEWL
- Avoid use of bar soaps
  - Bar soaps and the residue created by soap stored in a moist soap dish or washbasin may harbor bacteria and a bar of soap may be used on multiple patients contributing to the spread of bacteria. Avoid using water basins as they also harbor bacteria
  - Bar soaps used with washcloths can be very irritating, cause increased friction, and may remove oils from the skin, reducing the skin's barrier properties
- Consider use of a liquid soap. It is easier to dispense proper amounts of soap in liquid form
- Wash wipes can be used to keep the skin clean and free of irritation from urine and fecal material. They are soft, smooth, and gentle on delicate skin and are alcohol free
- Avoid alcohol and alkaline agents when picking a cleanser since they can be irritants and sensitizers, especially if skin integrity is compromised

Procedure:

- Thoroughly cleanse the genital area including the peri-anal area
- In women, cleanse from front to back as seen in this picture, to avoid spreading bowel bacteria from the rectum to the vagina and from the rectum to the urethra
- In men, cleanse from the glans, down the penile shaft and scrotum to the perianal area.
- After washing, let the skin dry rather than rubbing with a towel, to avoid irritation and skin tears



by evaporation or by sloughing off the application site, the substance may absorb, transferring into the tissue it is applied; and once absorbed, it will be metabolized, taken up and processed by the cells it enters [2]. Consequently, selection must be guided by a review of both the active and inactive product ingredients. Ingredient distribution in the cells is influenced by both the composition of the product and the condition of the skin application site [2]. This is related to the lipid content of the carrier substance and the solubility of the active ingredients in that substance. Higher lipid content correlates with higher tissue absorption and better cellular transfer of the active ingredients [2]. Skin condition at the application site also plays a role, as the presence of dermatitis will decrease product absorption [2]. In addition, higher lipid content creates a 'hydrophobic' product that will not adhere well to moist, desquamated tissue, resulting in product loss.

1. *Perineal cleansing* should be completed as soon as possible following an incontinent episode to limit the skin contact with urine and stool. Specialized perineal cleansers may be used as an alternative to soap and are available in a pH range consistent with the normal acid mantel of the skin, thus limiting damage to skin [26]. Cleansers may be supplied in a variety of forms, including liquids, foams (see Fig. 8.12) and impregnated towelettes. No-rinse cleansers simplify the skin care process and limit the risk of additional skin damage caused by incomplete removal of the product from the skin. In addition to these products, several products are available that combine cleansers, moisturizers and barrier functions in a single use towelette (see Table 8.7).
2. *Moisturizing* the skin daily is the second step in helping to keep the skin restored and well lubricated, and may have a cumulative effect. Loss of moisture from the SC causes dryness, increasing the risk for skin breakdown. The goal of moisturization is to repair the skin's function as a barrier by restoring its ability to attract, store, and redistribute water. Skin moisturizing products contain variable amounts of emollients, such as lanolin and humectants like glycerin or mineral oil to assist the skin in replacing lost lipids. Moisturizers are available alone or in combination with cleansers and moisture barrier products. There are several types of moisturizers or topical emollients. Product types include lotions, creams and ointments.
   - *Lotions* are composed of powder crystals dissolved in water and held in suspension by surfactants. They have the highest water content, evaporate more quickly, and therefore, need to be applied more frequently. Lotions are easy to apply, have a cooling effect, are non-occlusive, and don't leave a greasy film on the skin.
   - *Creams* are the most common moisturizer and they can be either oil in water (e.g., original Eucerin) or water in oil (e.g., basic cold cream) emulsions. They are more occlusive than lotions, and need to be applied frequently for maximum effectiveness.
   - *Ointments* are mixtures of water in oil and are most occlusive. The oil component can be either lanolin or petrolatum. Petrolatum felt to be more effective on skin and may have a more lasting effect than either lotions or creams.
3. *Protection*, an integral part of the skin care regime, involves providing an impermeable or semipermeable barrier on the skin to prevent or reduce the penetration of water and chemical and biological irritants found in stool and urine. Skin protection can be accomplished through utilization of a skin sealant, moisture barrier, or skin protectant. Skin sealants entail a combination of solvent and polymer, where the solvent dries and evaporates when applied to the skin and the polymer adheres to the skin, forming a barrier to moisture. Since alcohol is the primary solvent used, clinicians must note that these products are contraindicated in the presence of skin irritation and breakdown [27]. Moisture barriers are an alternative to skin sealant products. They are available in creams and ointments for application to intact or irritated skin, and protect against exposure to urine, feces, and perspiration. Creams are differentiated from ointments by the oil-to-water ratio of the products, with ointments having a smaller water to oil percentage. Moisture barriers are often comprised of zinc oxide, petrolatum, dimethicone,

Fig. 8.12 Foam cleanser (Secura®)—Courtesy of Smith-Nephew

Table 8.7 Manufacturers of skin products used for perineal care

	Medline	Sage	Coloplast	Convatec	Smith and Nephew	3 M
Cleanser	Soothe & Cool No-Rinse No Rinse Perineal Spray, Shampoo and Body wash	Comfort Bath Washcloths	Bedside Care No-Rinse shower/ bathwash	Aloe Vesta cleanser	Secura Personal Cleanser	
Moisturizer	Sooth & Cool skin cream, Remedy skin cream	NA	Sween cream Sween 24	Sensicare lotion	Secure Moisturizing Cream	Cavilon White Moisturizing Lotion
Moisture barrier	Remedy Olivamine Clear Aid	NA	Baza Clear, Critic Aid	Aloe Vesta Protective Ointment Sensicare Moisture Barrier	Secura Protective Ointment, Secura Dimethicone Protectant	Cavilon Durable Barrier Cream
Medicated products	Remedy Phytoplex Antifungal Ointment	2% Chlorhexidine Gluconate Cloths	Microguard cream or powder	Aloe Vesta 2-in-1 antifungal ointment	Secura Antifungal, Secura Antifungal Extra thick	
Sealants	Sureprep No-Sting Protective Barrier Wipe	NA	Brava Skin Barrier	Allkare Protective Barrier wipe	Skin Prep	Cavilon No Sting Barrier Film
Combination products	Remedy Olivamine Cleansing Body Lotion (cleanse + moisturize)	Impreva Bath Washcloths (cleanse + moisturize) Comfort Shield Barrier cloths (cleanse + moisturize + protect)	Baza Cleanse and Protect (cleanse + protect)	Aloe Vesta 2 in 1 (cleanse + moisturize)	Secura Moisturizing Cleanser (cleanse + moisturize)	

or a combination of these products (http://www.dermweb.com/therapy/common.htm):

- *Petrolatum* is a semisolid product derived from distilling off the lighter portions of petroleum (see Fig. 8.13a). It performs better as a barrier against skin maceration and protection against urine. It is less effective against stool, particularly liquid stool.
- *Dimethicone*, derived from silicone, is the least "greasy" of the above-mentioned products, and the least occlusive barrier [1, 27]. While there is limited research in this area, literature suggests that neither steroid, nor topical antimicrobials should be used as routine treatments for IAD [25].
- *Zinc oxide* is a white powder with mild antiseptic and stringent properties. It is typically combined with petrolatum (see Fig. 8.13b) providing a barrier against urine and stool [27]. This barrier, while a high performing barrier, can be difficult to remove from the skin. To remove zinc oxide paste, use mineral oil and avoid excessive scrubbing.
- *Films* are fast-drying and breathable liquid skin protectants. They are available as a foam applicator, wipe or spray bottle (see Fig. 8.13c). They contain a polymer dissolved in a solvent. Many contain alcohol. Once applied, they form a transparent protective coating on the skin. Films do not have active ingredients and can be removed with soap and warm water.

Patients experiencing IAD often develop cutaneous candidiasis requiring vigilant skin care and treatment of the fungal infection. Current evidence supports treatment with antifungal ointment or powder containing an azole (floconazole, miconazole) or allylamine (Butenafine) [1]. Several manufacturers offer products providing a moisture barrier with an antifungal in a dimethicone base which provides a soothing effect for patients suffering with this condition.

Skin care protocols for patients with IAD should be individualized based upon careful assessment of the patient's skin condition and their response to treatment. Successful prevention and treatment of IAD relies on treatment of underlying incontinence and implementation of and strict adherence to skin care protocols. Implementation of a skin care protocol is key to protecting intact skin in the individual with chronic incontinence when continence cannot be attained with available interventions and when incontinence resulting from acute illness (e.g., stroke or infection) limit the ability of the patient to avoid incontinent episodes [1, 25, 26].

Patient and Caregiver Education

Many patients with UI and/or FI may not be physically able to participate in education. Thorough patient assessment for learning readiness is essential. At minimum, all patients

Fig. 8.13 (**a**) Protective ointment with petrolatum (Aloe Vesta™)—Courtesy of Convatec, (**b**) thick moisture barrier zinc oxide paste for anorectal skin protection-(Critic-Aid® Skin Paste)—Courtesy of Coloplast Corp, (**c**) no sting barrier film (Cavilon™)—Courtesy of 3M

deserve an explanation of what care is being initiated no matter the patient's level of consciousness or demonstrated ability to participate. Frequently, other caregivers, especially family members, receive education on the prevention and management of IAD. Product manufacturer's and incontinence support groups often produce appropriate educational materials that can be distributed to caregivers. Written material for reference is essential when educating patients and families, to support and reinforce the education process.

Specific educational topics should address the key prevention and management concepts described in this chapter. The need for gentle cleansing as soon as the incontinence episode occurs should be emphasized. Instructions on how to use specific products for skin care or absorption and containment of urine and feces are essential. Instructions must follow manufacturer's guidelines. In addition, if the patient will be cared for at home, information on how and where to obtain supplies is required.

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